



## **COMMENTS OF W.M. BARR**

EPA Section 6(a) Rulemaking Regarding Methylene Chloride & N-Methylpyrrolidone  
Docket No. EPA-HQ-2016-0231  
Submitted May 19, 2017

### **EXECUTIVE SUMMARY**

For the reasons set forth in Barr's comments, as supported by the attached exhibits consisting of reports prepared by experts in the fields of toxicology, economics, the physical properties of chemicals, human factors, and risk assessment, it is apparent that EPA must withdraw those portions of the Agency's proposed "paint strippers" regulation that would prohibit retail sales of consumer-use paint strippers that contain methylene chloride (MeCl<sub>2</sub>) and N-methylpyrrolidone (NMP) because the Agency has not satisfied the legal requirements of Sections 6 and 26 of the Toxic Substances Control Act (TSCA). More specifically:

- The Agency's risk assessment does not meet the TSCA Section 6(a) legal standard because EPA has failed to demonstrate that an unreasonable risk is presented to users of retail-size paint strippers that contain MeCl<sub>2</sub> and NMP. The notice of proposed rulemaking (NPRM) relies on flawed hazard and exposure assessments that exaggerate the risks to consumer-users of retail-size paint strippers. In reaching its conclusions, EPA failed to critically examine and properly assess the data available on the reported exposure incidents involving paint remover products which prompted this rulemaking. The Agency also failed to critically consider information in the public domain concerning the abundance of similar incidents involving alternative paint stripper formulations. In the absence of actual data demonstrating that an unreasonable risk is presented by consumer use of retail-size containers of MeCl<sub>2</sub>- and NMP-containing paint strippers, EPA has relied on modeling methods to estimate consumer exposure based on assumptions about use patterns that are inconsistent with data in EPA's files on which the Agency relies for other purposes in the context of this rulemaking. This selective use of the data is not only arbitrary, it has led EPA to reach erroneous conclusions concerning the risks to consumers and residential remodeling contractors who purchase and use the retail-size paint stripping products EPA seeks to prohibit. By failing to consider such pertinent information, EPA has not relied on the best scientific methods, and cannot reasonably be said to have applied a weight of the evidence approach in reaching the determinations underlying the proposed rule. This lack of scientific rigor flies in the face of the standards Congress established for such rulemakings in its recent amendments to Section 26 of TSCA.
- The Agency's proposed rule also fails to meet the requirements of TSCA Section 6(c) which requires EPA to consider fully the benefits of chemical products it seeks to prohibit in one or more conditions of use and to determine that there are technically and economically feasible alternatives available that would benefit health or the environment if a specific condition of use of a substance were to be prohibited. EPA was in possession at the time of the proposal



of information demonstrating that MeCl<sub>2</sub>-containing formulations are singularly the most efficient and cost-effective paint remover products available at retail. NMP-containing stripper formulations are the second-most effective products in the retail sector. The materials in EPA's possession, and those which are reasonably available to the Agency, also clearly demonstrate that the alternative paint strippers currently available at retail do not work effectively. Consequently, EPA concluded incorrectly, and without proper substantiation, that alternative products are technically and economically feasible; thus, EPA has failed to meet the legal standards of Section 6(c).

- EPA has not properly considered the proposed rule's overall effect on the public health, and whether available alternatives will actually present fewer risks to consumers' human health or the environment than do retail-size containers of MeCl<sub>2</sub>- and NMP-containing paint strippers, as the Agency is required to do under Section 6(c). If retail purchasers must turn to these alternative products, they will be using less effective products to which they will be exposed for far greater periods of time -- presenting greater risk to their health and property, including fire hazards. In fact, the alternative paint stripper products available for retail sale to consumers are not demonstrably safer, particularly when compared to MeCl<sub>2</sub>-containing strippers.
- EPA has not met its legal obligations of the amended Section 6(c) to consider the economic consequences of the rule, including the likely effect of the rule on the economy, and small businesses in particular. By erroneously assuming that alternative products are similarly priced, equally effective, and lower-risk, EPA did not adequately nor accurately assess the true costs and lack of clear benefits of the proposed rule. The Agency's economic analysis contains numerous under-estimations of the costs of compliance that will be experienced by the formulators of retail paint stripper products and the costs the rule will impose on consumer and small business users of MeCl<sub>2</sub>- and NMP-containing paint strippers. Notwithstanding these underestimations, EPA's economic analysis reflects that the costs dramatically outweigh the benefits of the proposed prohibition on retail-size MeCl<sub>2</sub>- and NMP-containing paint strippers. In addition to failing to satisfy the requirements Congress imposed when amending Section 6(c), EPA failed to meet OMB's longstanding standards and EPA's own guidance regarding economic analyses of regulatory impacts.
- The amendments to Section 6(c) of TSCA also require EPA to conduct a credible review of alternative risk mitigation strategies, but the Agency has failed to do so. Instead, EPA considered a deliberately narrow range of alternative mitigation strategies for retail use paint strippers less severe than the proposed prohibition on retail-size containers it has ultimately chosen. For example, EPA did not consider use of vapor suppressants in MeCl<sub>2</sub> formulations, which the Agency's own Risk Assessment indicated would reduce airborne levels by as much as 50%. Additionally, without giving proper weight to all information available, EPA assumed consumer users of retail products will not comprehend and heed paint stripper label warnings. Consequently, EPA has not reasonably considered a regulatory strategy relying on enhanced product labeling in coordination with the Consumer Product



Safety Commission (CPSC). Such a coordinated approach is more consistent with the standards Congress imposed on the Agency under the amendments to TSCA Sections 6 and 9. The Agency has failed to meet its obligations to avoid unnecessary and duplicative regulations and to select and implement only those regulatory strategies necessary to mitigate risks to the extent necessary to reduce such risks to reasonable levels.

The materials we are providing with Barr's comments demonstrate that there are numerous deficiencies in EPA's record supporting the NPRM. EPA's proposal and the materials the Agency has compiled simply do not support a finding that consumer users and small business contractor users experience an unreasonable risk during residential use of retail-size paint removal products that contain MeCl<sub>2</sub> and/or NMP. The proposed regulation should be withdrawn and EPA should support and collaborate with CPSC to enhance labeling and risk communication efforts for the retail use of the paint removal products that EPA seeks to ban.



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## COMMENTS

### **I. The NPRM Fails to Satisfy Section 6(a) of TSCA Because EPA's Risk Assessment Does Not Demonstrate that Retail-Size Paint Strippers Containing MeCl<sub>2</sub> Pose an Unreasonable Risk to Users.**

EPA has proposed to prohibit the manufacture and processing of retail-size MeCl<sub>2</sub>- and NMP-containing paint remover products that are relied upon by consumer do-it-yourself (DIY) users and small business residential contractors. To justify this proposal, EPA proposes to make a determination that such uses present an unreasonable risk to consumers. However, the Agency's risk assessment for consumer uses of retail-size MeCl<sub>2</sub>- and NMP-containing paint strippers does not meet contemporary scientific standards and is therefore insufficient to support an unreasonable risk determination under the amendments to Sections 6 and 26 of TSCA.

#### **A. The NPRM relies on flawed hazard and exposure assessments that exaggerate risks and exposures to consumer-users of retail MeCl<sub>2</sub> paint strippers.**

##### **1. The point of departure used in EPA's Hazard Assessment to predict risks to consumers from MeCl<sub>2</sub>-containing paint strippers overstates risks.**

EPA completed a risk assessment for MeCl<sub>2</sub> use in paint strippers in 2014, concluding that residential and consumer uses of MeCl<sub>2</sub>-containing paint strippers could lead to acute (central nervous system or "CNS") effects in consumers and persons performing residential paint removal operations. The concerns for acute effects were based on a comparison between EPA's exposure predictions and the most conservative of four toxicological Points of Departure (PODs), all of which were identified from previously developed toxicity assessments of the methylene chloride data.<sup>1</sup> However, as discussed below, and in the report prepared by Dr. Lumpkin of CTEH,<sup>2</sup> by relying on candidate PODs from previously developed toxicity assessments, the Agency did not use contemporary best practices and methodologies that were available to the Agency at the time of its methylene chloride assessment. EPA did not derive its own POD and relied instead on its assessment of four different PODs taken from previously-performed assessments of acute human methylene chloride toxicity. The PODs for MeCl<sub>2</sub> were compared to seven acute exposure scenarios involving brush-on or spray-on applications in a hypothetical in-home workshop. The Agency's Multi-Chamber Concentration and Exposure Model (MCCEM) software was used to simulate the seven scenarios. The outcomes were

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<sup>1</sup> A POD is a chemical exposure level that represents an approximate threshold of adverse effects as identified in studies. Typically, the POD is derived from a No Observed or estimated No Observed Adverse Effects Level (NOAEL) -- a dose level that does not produce an adverse effect in a particular species studied.

<sup>2</sup> Michael H. Lumpkin, Center for Toxicology & Environmental Health, *Comments on the Health Risk Basis for U.S. Environmental Protection Agency's Proposed Regulation of Certain Uses of Methylene Chloride and N-Methylpyrrolidone Under TSCA 6(a)* (May 2017), attached hereto as Exhibit 1.



compared to EPA's selected PODs to conclude, erroneously, that consumer and residential users would be expected to be overcome by MeCl<sub>2</sub> fumes, suffer dizziness and confusion, and potentially expire.

When examined critically, as Dr. Lumpkin has done, it is apparent that the Agency's 2014 MeCl<sub>2</sub> risk assessment (and the related supplemental materials prepared after EPA submitted the proposed rule to OMB for review) overestimates risks from residential use exposures and rely on the use of various overly-conservative "off-the-shelf" assessments, which appear to have been selected to arrive at EPA's foregone conclusions about risks from consumer and residential uses of MeCl<sub>2</sub>-containing paint stripper products. Additionally, in reaching determinations on MeCl<sub>2</sub>, EPA chose not to use the same scientific methods that it relied upon when assessing NMP. Thus, the Agency, in preparing its Risk Assessment, cannot be said to have considered all information reasonably available, nor to have used the best available scientific methods as it is required to do under the amendments to Section 26 of TSCA.

*Dr. Lumpkin's report explains how the Agency's use and interpretation of its selected Points of Departure (PODs) does not reflect the best available science.* EPA's risk assessment for MeCl<sub>2</sub> considered as many as 4 different PODs based on existing assessments performed by other regulatory agencies. Curiously, for MeCl<sub>2</sub>, unlike for NMP, the Agency did not generate its own POD based on the entirety of information known to EPA concerning the effects of MeCl<sub>2</sub> and the weight of the evidence. EPA decided instead to rely exclusively on a single POD for MeCl<sub>2</sub>, based on a POD derived to be protective of "exercising coronary heart disease patients from angina."<sup>3</sup> EPA could have, but did not, consider a situational-specific POD designed to evaluate accurately the exposures typical to consumer and residential uses of MeCl<sub>2</sub> paint strippers. Data in the open literature have shown that CNS effects experienced during use of MeCl<sub>2</sub> are transient in nature when the use is of limited duration. Consumer and residential uses of MeCl<sub>2</sub> strippers are by their nature episodic and for short durations.

In selecting a POD for MeCl<sub>2</sub>, the Agency used the most restrictive POD, rather than applying the scientific methods that were used by the National Academy of Sciences (NAS) in generating its Acute Exposure Guideline Levels (AEGLs). The AEGLs are expected to protect "the general population, *including susceptible individuals*, [from experiencing] irreversible or other serious, long-lasting adverse health effects, or an impaired ability to escape."<sup>4</sup> The AEGL values were derived using a Physiologically Based Pharmacokinetic (PBPK) model to simulate brain, blood, and inhaled air levels of methylene chloride for specific potential exposures, employing methods

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<sup>3</sup> Elizabeth N. Allred, et al., *Short-Term Effects of Carbon Monoxide Exposure on the Exercise Performance of Subjects with Coronary Artery Disease*, 321(23) New Eng. J. Med. 1426 (1989) (cited in Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014)).

<sup>4</sup> National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances, *Methylene Chloride: Interim Acute Exposure Guidelines Levels (AEGLs)* (2009), [https://www.epa.gov/sites/production/files/2014-08/documents/methylene\\_chloride\\_interim\\_dec\\_2008\\_v1.pdf](https://www.epa.gov/sites/production/files/2014-08/documents/methylene_chloride_interim_dec_2008_v1.pdf).



that are closer to the modern state of the science than the methods used to generate the POD selected by EPA. By selecting the most conservative POD for estimating risks to consumers, the Agency also rejected use of the acute Reference Exposure Level (REL) POD derived by the state of California's Office of Environmental Health Hazard Assessment (OEHHA), even though the California POD is expected to represent an exposure level "at or below which no adverse health effects are anticipated in a human population, *including sensitive subgroups*, exposed on an intermittent basis."<sup>5</sup>

*EPA should have selected a PBPK-based model to develop a contemporary POD that used the best available scientific methods for assessing the acute effects from MeCl<sub>2</sub>.*<sup>6</sup> The advantages of using PBPK models to assess human health risks are well-established. The NAS has repeatedly recognized the use of PBPK models for this purpose. Such models have been used by EPA itself to derive chronic human toxicity values for multiple chemicals, including for methylene chloride in the context of its IRIS assessment. Moreover, EPA adopted such a model to assess risks from exposure to NMP. The PBPK techniques are both well understood and actually used by EPA, including in the context of this proposed rulemaking. However, rather than undertaking the kind of high-quality evaluation and risk assessment called for by the amended Section 26 of TSCA, and applying a PBPK-based model to establish more contemporary PODs, the Agency instead assigned multiple uncertainty factors to benchmark margin of exposure (MOEs) derived using PODs that were generated by other regulatory and scientific bodies. EPA's POD and benchmark MOE selection thus introduced unnecessary scientific uncertainty into the estimation of acute health hazards. This inevitably led to the erroneous conclusion that consumer-users of paint strippers might be at risk.

By not using the best available science and methodologies for POD determination, EPA established benchmark Margins of Exposure (MOE values accounting for POD uncertainty) that exaggerated the scientific uncertainty. This problem could easily have been avoided if EPA had selected one of the PBPK model-based AEGL values, or if EPA had developed a POD by using the 2011 IRIS PBPK model. By choosing to use less advanced scientific methods, EPA factored in an unnecessary level of conservatism that tainted the 2014 risk assessment.

2. *In its Exposure Assessment for consumer-use, EPA applies modeling assumptions that are overly conservative and that unrealistically exaggerate residential exposures.*

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<sup>5</sup> OEHHA (Office of Environmental Health Hazard Assessment), State of California Environmental Protection Agency, *Air Toxics Hot Spots Program Risk Assessment Guidelines. Part I: The Determination of Acute Reference Exposure Levels for Airborne Toxicants* (1999), <https://oehha.ca.gov/media/downloads/cnr/acutereel.pdf>.

<sup>6</sup> A PBPK model is a computer simulation of chemical uptake, distribution, metabolism, and elimination in the body, using mathematical representations of physiological, biological, and biochemical processes to predict tissue levels of a particular chemical following exposure.





EPA explains in Section 3.2 and Appendix H of its risk assessment that there is a lack of measured data from monitoring studies that are sufficiently reliable for risk assessment purposes. As noted above, the Agency used an MCCEM software tool to simulate the seven exposure scenarios. However, those scenarios that suggest an unreasonable risk for consumer and residential users of retail MeCl<sub>2</sub> paint strippers are inappropriate for a number of reasons.

*Bathtub stripping scenarios should not be included in consumer-use exposure estimations.* EPA has included bathtub stripping as a use scenario, even though MeCl<sub>2</sub> product labels now advise consumers that this is not a safe use for MeCl<sub>2</sub> products. When that use scenario is excluded from the MCCEM, as Dr. Lumpkin's report suggested, the risk to consumers (even using the most conservative of PODs) is greatly diminished. Moreover, EPA's own Risk Assessment, in describing the methods used for modeling consumer exposures, states that the "bathroom scenario... was assumed to be performed by a professional, as opposed to a consumer."<sup>7</sup> Consistent with this, the survey conducted for the CPSC includes no reference to bathtub stripping as an activity in which consumers typically engage.<sup>8</sup> Significantly, the handful of fatality incidents EPA cites in the Preamble which are involving bathtub stripping are associated with professional, not consumer, stripper activities.<sup>9</sup> Nevertheless, EPA's model is specifically engineered to ensure that the levels of exposure in a consumer bathroom will approximate those noted in a NIOSH report of a specific incident involving a fatality. Thus, for EPA's model to be considered a "reasonable" representation of consumer-use scenarios, the bathtub stripping use should be excluded.<sup>10</sup>

*EPA's consumer exposure model failed to include outdoor use scenarios.* In explaining the Agency's Modeling Parameters for consumer-use scenarios, EPA's Risk Assessment repeatedly cites to and relies upon the CPSC's consumer survey of methylene chloride consumer paint stripper users.<sup>11</sup> However, the Agency's model for consumer exposure arbitrarily ignores the

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<sup>7</sup> Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0272&contentType=pdf>, at Appendix H, pg. 224.

<sup>8</sup> Lyria Boast, ABT Associates, Prepared for the U.S. Consumer Product Safety Commission, *Methylene Chloride Consumer Use Study Survey Findings*, CPSC Contract # CPSC-C-89-2032 (March 1992), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0107&contentType=pdf>.

<sup>9</sup> Analyses of fatalities and incident reports as provided in the reports of Dr. Kingston and Mr. Hall, attached hereto as Exhibits 2 and 3, respectively.

<sup>10</sup> Even if the Agency were to consider bathtub stripping to be a reasonably foreseeable use, notwithstanding the retail product labeling, EPA has the authority to propose a Section 6(a) regulation that is targeted more deliberately and specifically to prohibit the use of retail MeCl<sub>2</sub> stripper products for bath tub stripping uses. This is an approach that also is within the authority of the CPSC, and it is within EPA's discretion to defer to that agency to regulate this class of consumer products in that particular manner. (As discussed elsewhere in these comments, the HSIA petition pending before CPSC will enable such an action to be taken more swiftly and effectively by CPSC for consumer-use MeCl<sub>2</sub> strippers than EPA's current proposed MeCl<sub>2</sub> rulemaking.)

<sup>11</sup> See e.g., Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014), at Section 3.2.3.



fact that the same consumer survey data makes clear that the *predominant site* where consumers use MeCl<sub>2</sub> paint strippers is outdoors, and a basement is the *least often used indoor use site* for consumers. In a separate publication to which EPA cites for other purposes, it is noted that 60 percent of paint stripper users report they use MeCl<sub>2</sub> products outdoors.<sup>12</sup> Instead, the MCCEM model and EPA's Risk Assessment assume all consumer uses will occur indoors. Clearly, in designing its consumer modeling program, EPA has selectively relied on the CPSC survey data for some (e.g., the quantity of MeCl<sub>2</sub> stripper used) but not all features of its model design (e.g., the frequency of outdoor use).

Apparently aware that the consumer exposure scenarios modeled might not present as stark a risk expression as would dictate the draconian regulatory action the Agency has been proposed, EPA undertook additional exposure modeling exercises for consumer uses. Thus, in its 2016 Supplemental Analysis—performed without the benefit of peer review—EPA expanded the “typical” use scenarios to specifically include larger, not smaller, DIY jobs and to include repeated applications of paint strippers in the bath tub stripping portion of its model. However, although EPA again cites the CPSC Consumer User Survey prepared by Abt Associates in the justifications presented in its Supplement Analysis, outdoor use scenarios were neither contemplated nor added. At the same time, EPA continued to expand and adjust the parameters and inputs for new scenarios to be modeled -- except, notably, for any outdoor use scenario. EPA has behaved arbitrarily by failing to give due consideration in its exposure modeling and risk assessment to the fact that consumers report outdoor use to be the most common setting for their use of MeCl<sub>2</sub>-containing paint strippers.

It is worth noting that the use of modeling was made necessary because of the lack of reliable measured values from monitoring studies. Apparently, the *only* measured values from existing monitoring studies EPA considered to be reliable were those taken during a 1994 study -- for which EPA admits absolutely *no records were kept* about the concentration of MeCl<sub>2</sub> in the paint strippers used, making the validity of the data themselves questionable and potentially without scientific merit.<sup>13</sup>

EPA's model artificially “double doses” the rate of MeCl<sub>2</sub> stripper application. Even though information provided by Barr from its 2015 Report<sup>14</sup> was provided to the Agency prior to its completion of the Supplemental Analysis of consumer exposure in 2016, EPA continued to build

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<sup>12</sup> Donna M. Riley *et al.*, *Evaluating the Effectiveness of Risk-Reduction Strategies for Consumer Chemical Products*. Risk Analysis, Vol. 21 (2001), <http://sds.hss.cmu.edu/risk/articles/EffectConsumerChem.pdf>.

<sup>13</sup> See Environmental Protection Agency, *Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal* (Nov. 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0254&contentType=pdf>; Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014), at Appendix H.

<sup>14</sup> W.M. Barr & Company, *Identification and Comparison of Solvents and Paint Removers as Alternatives to Methylene Chloride in Paint Removal Applications* (Aug. 2015), attached hereto as Exhibit 4.



and expand on use assumptions for MeCl<sub>2</sub> products that artificially contrive a second product application by consumers.<sup>15</sup> The assumption that a second application of MeCl<sub>2</sub> strippers is routinely required inappropriately increases the quantity of MeCl<sub>2</sub> to which consumers could be exposed. Moreover, the assumption regarding the need for a second application directly contradicts the Barr Report from 2015 (and updated for 2017) and virtually all other evidence available to EPA that MeCl<sub>2</sub> efficiently and effectively removes multiple layers (coats) in minutes from almost any coated surface following a single application.<sup>16</sup>

*The MCCEM also does not provide a reasonable worst case depiction of consumer residential uses of MeCl<sub>2</sub> products because it overstates the length of time users and bystanders use MeCl<sub>2</sub> strippers.* The CPSC Consumer Users Survey notes that most MeCl<sub>2</sub> users reported that they were spending less time in the room during use, on average, than was reported in results from prior year's surveys and that more users specifically reported leaving the room immediately.<sup>17</sup> The most recent CPSC survey data reflected that, on average, consumer users exited the room after 12 minutes.<sup>18</sup> This figure is reasonable given the results observed in the two Barr reports, which demonstrate MeCl<sub>2</sub> is effective at removing all coatings from multiple layers on almost any surface within the first 15 minutes after application. Moreover, retail use stripper product labels advise consumers that leaving a paint stripper product in place to dry after it has effectively loosened coating will lead to disappointing results. It is not reasonable for EPA to assume for purposes of its exposure modeling that a consumer-user of a retail MeCl<sub>2</sub> paint stripper will leave the product in place for a significantly longer period than the directions instruct.

Likewise, the model overstates a reasonable worst case consumer exposure for residential users and bystanders because it does not take into account that MeCl<sub>2</sub> users are extremely unlikely to remain indoors for a 24-hour period following product use. This is made clear by the CPSC User Survey. Specifically, as described in the Survey, consumers generally follow MeCl<sub>2</sub> stripper label directions -- including scraping and disposing of the removed coating soon after the stripping step has been completed. Thus, in light of the CPSC Survey results, and taking into account comparative product efficacy (as demonstrated in the 2015 and 2017 Barr Reports), EPA should have incorporated into its model the fact that the clean-up step will be performed more quickly following MeCl<sub>2</sub> product application than for any of the other formulations of retail use stripper products under consideration by EPA. Moreover, clean-up activities will result in

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<sup>15</sup> See Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014), at Appendix H.

<sup>16</sup> Nevertheless, when performing other technical assessments (notably its Alternatives Analysis and its Economic Analysis), EPA generously assumed that other formulations (e.g. benzyl alcohol strippers) were equally effective or more effective than MeCl<sub>2</sub> paint strippers, and thus would not require repeat applications.

<sup>17</sup> Lyria Boast, ABT Associates, Prepared for the U.S. Consumer Product Safety Commission, *Methylene Chloride Consumer Use Study Survey Findings*, CPSC Contract # CPSC-C-89-2032 (March 1992),

<https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0107&contentType=pdf>.

<sup>18</sup> *Id.*



increased ventilation in the work area and more frequent air exchanges throughout the residence, which will considerably mitigate residual exposures to the user, and to building occupants and bystanders.

*EPA's consumer exposure model (as expanded by its non-peer reviewed supplemental analysis) does not reflect the best available science.* In the absence of reliable data to predict consumer user exposures to MeCl<sub>2</sub> strippers, EPA has chosen to rely on the use of modeling rather than undertaking a contemporary exposure and monitoring study. It is likely EPA could have saved considerable Agency resources and staff and contractor time if it had simply commissioned a credible monitoring study using methods that could be validated by peer reviewers, coupled with currently available retail paint stripper products -- thereby obtaining measured observations and study results capable of repetition. Instead of utilizing the best available science, EPA has chosen to cherry pick information from differing sources to inform its consumer exposure model, which it repeatedly modified while expanding the scenarios evaluated, until EPA created a basis to support the complete prohibition on consumer-use MeCl<sub>2</sub> products that the Agency preferred all along.

3. *EPA must reexamine its risk assessment, and apply the best scientific methods to critically reassess the risks to human health during typical consumer and residential remodeler uses of MeCl<sub>2</sub> products.*

To remedy these deficiencies, EPA should employ a modified PBPK model, such as the kind used during the 2011 IRIS risk assessment for chronic effects from MeCl<sub>2</sub>. This would be an important first step in aligning the risk assessment methodology for estimating potential risks to consumer DIY-ers and residential contract remodelers with the Agency's own current scientific standards and CTEH's technical recommendations. Furthermore, the most advanced, vetted, and available PBPK model for MeCl<sub>2</sub> should be used to take into account variability in population physiology, metabolic capacity, variations in COHb production, and exposure duration-specific effects on internal doses of blood MeCl<sub>2</sub> and COHb levels. On a parallel path, EPA should either a) conduct an exposure study to take measurements based on real-life consumer/residential paint stripping scenarios (including an outdoor use scenario); or b) completely rebuild its consumer-use exposure model to reasonably reflect the predominance of outdoor uses and all of the other information about the duration and locations of consumer uses available to EPA. The newly-derived POD could be factored into a new risk assessment relying on either the results of a new monitoring study or the rebuilt consumer exposure model. The resulting analysis would better reflect the information reasonably available to EPA and the use of more contemporary scientific methods. Appropriately generated MOEs will enable EPA to more credibly assess



whether consumers and residential remodeler users of retail MeCl<sub>2</sub>-containing paint stripping products who abide by the label instructions experience an unreasonable risk to their health.<sup>19</sup>

**B. EPA's failure to independently assess available data on fatalities and incident reports, and its reliance on a third party's flawed assessment, led to an exaggeration in exposure incidents for MeCl<sub>2</sub> products.**

EPA suggests it is reasonable to conclude that retail-size MeCl<sub>2</sub> paint strippers pose an "unreasonable risk" to consumers based almost entirely on modeling of acute exposures, in both a consumer and an occupational setting. But modelling data describes *theoretical* risk. To understand *actual* risk, it is necessary to gather data on actual instances of exposure, and the consequences of such exposures. Fortunately, databases of exposures and adverse effects events are available to provide data concerning actual risk posed by MeCl<sub>2</sub>-containing paint removal products. A careful evaluation of those data provide a better understanding of the real-world risks posed to consumers and other users from the retail products EPA seeks to regulate. However, Agency staff did not personally undertake such an analysis.

1. EPA failed to adequately assess the incident data that show a small number of reported significant incidents from MeCl<sub>2</sub> paint stripper exposures, an even smaller number of such incidents attributable to consumer uses, and an overall decline in such incidents by almost 80% during the preceding 15-year period.

Although EPA is required by statute to consider all information reasonably available and to use the best available science to reach weight of the evidence determinations, EPA did not undertake its own, independent, evaluation of such incident data. Instead the Agency relied, in part, on a publication by a public interest organization which summarizes reports of approximately 56 fatalities involving users of MeCl<sub>2</sub> products that occurred over a 40-year period and poison control center data reported during a five-year period (the CPI Report).<sup>20</sup>

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<sup>19</sup> In his report, Dr. Lumpkin addresses the Agency's risk evaluation for consumer uses of NMP-containing paint stripper products which we do not address here for reasons of brevity. However, the report documents that EPA elected to apply PBPK analysis in that context and thus demonstrated its capacity and willingness to apply these more contemporaneous scientific methods. The CTEH report also identifies several ways in which the Agency's NMP risk assessment relied on unnecessary uncertainty factors in the NMP context to overstate risk to consumer users. EPA is encouraged to consult Dr. Lumpkin's report and, in light of CTEH's observations, reconsider accordingly the Agency's own assessment of risks to residential consumer users of retail NMP-containing paint strippers.

<sup>20</sup> Jamie Smith Hopkins, *Common Solvent Keeps Killing Workers, Consumers*, The Center for Public Integrity (Sept. 21, 2015), <https://www.publicintegrity.org/2015/09/21/17991/common-solvent-keeps-killing-workers-consumers>.



Barr has provided a report by Dr. Richard Kingston of Safety, Science & Toxicology Associates LLC<sup>21</sup>, which evaluates the CPI Report and the most recent 16 years of data available from the American Association of Poison Control Centers (AAPCC) database.<sup>22</sup> Dr. Kingston has concluded that the incident data do not support EPA's findings about the theoretical risk posed by MeCl2 paint remover products. Moreover, CPI's incomplete review of the incident data contains many flawed conclusions and fails to consider important trends in the data. The incident data upon which the Agency relied do not provide a basis to propose a complete ban on retail-size, consumer-use paint and coating removal products containing MeCl2 for the many reasons set forth, and the extensive data contained, in Dr. Kingston's report.

The vast majority of the identified fatality incidents in the CPI report resulted from occupational, rather than consumer uses, and thus do not support a conclusion that there is an unreasonable risk to consumers from retail MeCl2 paint strippers when used in accordance with the label. The one reported fatality apparently resulting from a consumer exposure that was identified in the documents relied upon by EPA involved confounding factors that impacted the exposure scenario and outcome (i.e., multiple chemicals at issue).

CPI's review of AAPCC incident data involving MeCl2 paint strippers contained noteworthy flaws and oversights including consideration of reported exposure incidents that are not within the AAPCC consumer categories for paint stripper products. The CPI report cited 2,700 exposure incidents reported in the 5-year period ending in 2013. However, these data do not fairly reflect the category of paint stripper products addressed in EPA's proposed rulemaking. In fact, there were only 1,695 reported exposures during the period covered relating to MeCl2 paint strippers. Moreover, the CPI report stated that there were "about 950" exposures where individuals sought medical attention when, in fact, that number was 627 in the pertinent category of paint strippers. These flaws, and the others documented below, undermine the credibility of the CPI report and demonstrate that EPA's conclusions about the incident data are not based on substantial evidence in the record.

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<sup>21</sup> Dr. Richard Kingston, Safety, Science & Toxicology Associates, *Paint Stripping Agents & Adverse Event Data Trends* (May 2017), attached hereto as Exhibit 2.

<sup>22</sup> The AAPCC provides a central clearinghouse of information on exposure incidents to chemicals and other potential toxins. The Poison Control Centers operate government funded "hotlines" throughout the United States to field calls from individuals who believe they may have been exposed to a hazardous substance. The hotlines are staffed by health professionals who provide guidance to callers as to whether the exposure may result in adverse effects, and if so to recommend home treatment or referral to a health care facility.

2. EPA's proposal ignores the significant drop in reported exposures to MeCl2 paint strippers over the past 15-years.<sup>23</sup>

The significant downward trend in reported exposures was clearly evident in the five year period ending in 2013, the period of time apparently covered in the CPI Report. This was true even during the preceding 10-year period. Dr. Kingston's evaluation of the poison control incident data demonstrates that consumer exposures to MeCl2-containing paint strippers have been steadily declining since 2000, as has the incidence of significant outcomes and hospital referrals, despite steady sales of MeCl2-containing paint strippers in the retail consumer product market. These data suggest that the weight of the evidence on consumer exposures to paint stripper products does not support the Agency's assessment of an unreasonable risk associated with residential consumer-use of MeCl2 paint stripper products.

Dr. Kingston's report also notes (as discussed in greater depth in Section III.D. below) that alternative paint stripper products represented in the "Non-MeCl2" paint stripper product category of the AAPCC database are far more frequent than MeCl2 paint strippers. These poison control center exposure incident data suggest that non-MeCl2 paint strippers currently pose a greater hazard than MeCl2 paint strippers. This is especially noteworthy if market share data are taken into consideration. These data, which are reasonably available to EPA, strongly suggest that a mandatory transition to non-MeCl2 paint strippers in the consumer-use market will result in an increase in exposure incident reports to poison control centers attributed to non-MeCl2 paint strippers.

3. EPA cites additional sources on fatalities which do not support its consumer-use concerns

In its proposed rulemaking, EPA expressed concerns about consumer users based in part on fatal incidents involving the use of methylene chloride.<sup>24</sup> Steven Hall of Applied Safety and Ergonomics (ASE) has independently reviewed the publications EPA cited regarding these incidents.<sup>25</sup> The citations included references covering the preceding 40-year period (1976 -

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<sup>23</sup> Since 1984, AAPCC has published annual reports summarizing incident information from the call centers, broken down by individual product category. For paint removal products, the annual reports contain three distinct categories: (i) Paint and Stripping Agents: Stripping Agents: Methylene Chloride; (2) Paints and Stripping Agents: Stripping Agents: Other Types of Stripping Agents; and (3) Paints and Stripping Agents: Stripping Agents: Unknown Types of Stripping Agents. This division allows for a simplified review of incidents associated with the MeCl2 stripping agents at issue in this rulemaking, since this category of products has its own category in the annual reports.

<sup>24</sup> "EPA has identified 49 fatalities since 1976 resulting from consumer or commercial worker exposure to methylene chloride during paint and coating removal, including for uses not proposed for regulation." 82 Fed. Reg. 7,464, 7,482 (Jan. 19, 2017). EPA continues, the "...deaths are not limited to commercial users or occupational bystanders... [c]onsumer fatalities have been recorded..." *Id.* at 7,483.

<sup>25</sup> Steven Hall, Applied Safety & Ergonomics, *Response to EPA Analysis Regarding Methylene Chloride Paint Remover as a Potential Risk Mitigation* (May 2017), attached hereto as Exhibit 3.



2016). The incidents described in the documents relied upon by EPA are not mutually exclusive and thus contain repetitive accounts of specific fatal accidents. ASE's analysis determined a number of these incidents did not involve paint or coating removal, but rather involved other activities such as applying glue. Of the fatalities noted by EPA and evaluated by ASE during the nearly 40-year period covered by the data, the vast majority involved occupational users. Only one report specifically involved a consumer (an 80-year-old consumer who was also exposed to an additional chemical); and for one other report the circumstances and purposes of the MeCl<sub>2</sub> use could not be determined based on the information available. Some of the occupational fatalities involved the use of dip tanks in commercial settings (furniture stripping) and others involving use in enclosed environments (e.g., cleaning the interior of industrial tanks). Although fatalities have occurred in recent years while bathtub stripping was being performed, these were commercial/professional users, and none of the fatal bathtub stripping incidents involved consumer users.

For the reasons set forth in Sections I.A. and I.B. above, EPA's assessment of risks to consumer users of retail MeCl<sub>2</sub> paint strippers does not reflect the best available science, and the Agency did not apply a weight of the scientific evidence approach when evaluating the published accounts of fatalities and other reports of exposure incidents. It is clear the record does not support the proposed unreasonable risk finding on which EPA relies to support the NPRM prohibiting retail-size consumer-use MeCl<sub>2</sub> products.

## **II. EPA Failed to Satisfy the Requirements of TSCA Section 6(c) Because the Agency Erroneously Concluded Technically and Economically Feasible Alternative Paint Strippers Exist and the Agency Failed to Adequately Consider the Costs and Benefits of its Proposal.**

The amendments to TSCA Section 6 were intended, in part, to ensure that EPA was not unnecessarily impeded in regulating substances that present unreasonable risks. However, Congress did not relieve the Agency of its duty to regulate carefully and reasonably. Thus, the amended Section 6(c) still requires EPA to consider: (i) the benefits of a substance and its conditions of use; (ii) the availability of effective and affordable alternative substances; (iii) alternative ways EPA can mitigate such risks; and (iv) the costs and burdens such regulations impose on the economy, small business and users. In this proposed rulemaking, EPA has failed to meet its Section 6(c) obligations.

### **A. EPA did not objectively assess the benefits of retail-size consumer-use MeCl<sub>2</sub> paint strippers.**

EPA failed to acknowledge numerous benefits of retail-size containers of MeCl<sub>2</sub> strippers. The smaller sizes of retail use MeCl<sub>2</sub> paint strippers reduce the opportunities for accidental spills and environmental releases. Smaller containers considerably reduce storage of excess products and diminish unnecessary waste. The use of smaller containers also reduces the opportunity for





accidental exposures, including those resulting from misuse by unintentional users, such as minors.

As noted above, in July 2016, well in advance of EPA's publication of the proposed rule, and as part of the Agency's small business consultation process, Barr provided EPA with a copy of the Company's 2015 Report which compared the efficacy of numerous alternative commercially-available paint stripper products.<sup>26</sup> In 2017, Barr developed a revised report to supplement its 2015 report. Barr's 2017 Report compared various coating remover formulations using similar test methods.<sup>27</sup> It also carefully addressed several experimental formulations to provide the Company, and now the Agency, with insights into the ways in which technological innovations might move the industry forward when devising potential improvements for retail, consumer-use paint strippers. Barr's testing methods are consistent with the industry-wide standard for determining the efficacy of paint stripping products, as described in ASTM D6189 - 97.<sup>28</sup>

Barr's 2015 and 2017 Reports both unequivocally demonstrate the clear-cut benefits of consumer-use MeCl<sub>2</sub> paint strippers that other commercially available non-MeCl<sub>2</sub> products do not possess. Non-MeCl<sub>2</sub> paint strippers made available through retail outlets for consumer use and for use by small business commercial and residential paint and remodeling contractors are uniformly less effective, require longer periods of time to work (if they work at all), are more expensive to use and contribute to longer periods of user exposure to paint strippers.

In contrast to the Barr methodology, EPA relied on largely qualitative information for assessing the technical and economic feasibility of alternative paint stripping products, and published reports that compared only the reported health effects of alternative products, but which did not evaluate their effectiveness. For reasons that remain unexplained, the Agency did not make reference to the 2015 Barr Report in the preamble to the proposed rule.

**B. Technically feasible alternatives to MeCl<sub>2</sub>-containing paint removers do not exist.**

When EPA is weighing a restriction to or prohibition of the use of a substance, the Agency is required under TSCA Section 6(c)(2)(c), to consider, among other factors, whether "technically and economically feasible alternatives" to the substance being regulated, "will be reasonably available." EPA is also required to consider whether such alternatives will provide a

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<sup>26</sup> The 2015 Barr report also was referenced and discussed in the context of face-to-face meetings Barr had with EPA personnel prior to the proposed rule's publication.

<sup>27</sup> W.M. Barr & Company, *Identification and Comparison of Solvents and Paint Removers as Alternatives to Methylene Chloride in Paint Removal Applications* (March 2017), attached hereto as Exhibit 5.

<sup>28</sup> ASTM International, *Standard Practice for Evaluating the Efficiency of Chemical Removers for Organic Coatings*, D6189 - 97 (Reapproved 2014), attached hereto as Exhibit 10 (and submitted under separate cover to EPA), establishes practices to evaluate the effectiveness of coating removers used on clear or pigmented coatings as applied to wood and metal.

comparatively better “risk profile” to the user. This requires careful analysis. Simultaneously, the Agency is charged in the amended Section 26 of TSCA to consider reasonably available information, and to evaluate the totality of the data, assess its credibility and finally to apply a “weight of the scientific evidence” standard.<sup>29</sup> This obligation applies equally to assessing the technical and economic feasibility of alternatives and to the comparative risks resulting from their use in practice.

As an initial matter, EPA’s conclusion that there are technically feasible alternatives to MeCl<sub>2</sub>-containing paint removers is based primarily on the mere fact that any alternative removers exist, even where the alternatives are more costly and less effective than MeCl<sub>2</sub> products. EPA’s mandate to identify technically and economically feasible alternatives necessarily requires EPA to identify products that are equivalent to MeCl<sub>2</sub> products in cost and effectiveness. EPA does not in the preamble define what it means by “technically and economically feasible” alternatives, but -- as will be shown below -- EPA does not demonstrate that the alternatives to MeCl<sub>2</sub> products are comparable in terms of cost or effectiveness.

To the extent EPA cites to information on the performance of alternative products, the reports it relies upon are anecdotal and qualitative. For example, in support of its conclusions that benzyl alcohol; acetone, toluene and methanol (ATM); and caustic chemicals are technically feasible alternatives, EPA frequently cites to the Small Business Advocacy Review Panel Report and its Summary of Stakeholder Engagement.<sup>30</sup> Both of these reports contain statements from stakeholders which support EPA’s conclusion that some stakeholders use alternatives to MeCl<sub>2</sub>-containing products. However these reports also contain many statements from stakeholders who either did not mention the efficacy of specific alternatives (even when prompted to do so during a survey) or who identified the many limitations of these alternatives.<sup>31</sup> While EPA is correct in stating that the contractor-prepared reports confirm the existence of potential alternatives to MeCl<sub>2</sub>-containing products exist, they do not support the conclusion that these alternatives are comparatively as effective.

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<sup>29</sup> 15 U.S.C. § 2625 (i), (k).

<sup>30</sup> 82 Fed. Reg. at 7,485-86 (Jan. 19, 2017).

<sup>31</sup> See, e.g., Environmental Protection Agency, *Summary of Stakeholder Engagement on Methylene Chloride and N-Methylpyrrolidone in Paint and Coating Removal*, Response of Home Depot (Aug. 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0252&contentType=pdf>, at pp. 5-6 (“Substitute products range in popularity, based on perceived efficacy. Have had to remove some products due to lack of sales.”); Response of Experimental Aircraft Association (“Negative experiences with alternatives; found one that seemed to work, but it turned out to contain methylene chloride.”).



1. Documents in EPA's possession directly dispute the Agency's conclusion about the technical feasibility of alternatives to MeCl2-based consumer-use products.

As noted above, Barr prepared a comparative assessment of alternative formulations in 2015 which the Company provided to EPA in 2016 (*before* the proposed rule was issued and before EPA's own Alternatives Analysis was completed). The 2015 Barr Report showed that paint removal products containing MeCl2 clearly outperform all of the alternative products EPA has identified, particularly for consumer, do-it-yourself (DIY) and limited duration use applications. The testing was performed on a variety of coatings on specific substrates. As the 2015 Barr Report demonstrates, chemical solvent alternatives such as ATM and benzyl alcohol do not completely remove alkyd or epoxy paints in fewer than four hours and in some cases do not remove them at all. In contrast, these results reflect that MeCl2-based paint removal products removed both kinds of coatings from substrates within five minutes on all painted surfaces tested, and within 15 minutes on cured coatings. Products containing NMP performed better than the other alternatives identified by EPA, but not as well as MeCl2.

The findings of Barr's 2015 Report are echoed in the Company's experience in the marketplace with alternative formulations that do not contain MeCl2. Barr has, on multiple occasions, launched new products with alternative formulations only to find that consumer acceptance has been dismal. The Company has received feedback in those instances from its customers that the products do not remove all varieties of coatings and do not work as quickly. In sum, Barr's experience suggests that users are routinely disappointed by the performance of alternatively formulated products. Barr has updated its 2015 Report, and the updated assessment affirms the 2015 results (as is discussed in further detail below). This conclusion about customer preferences is verified by EPA's own Summary of Stakeholder Engagement for this rulemaking,<sup>32</sup> which summarized the comments of numerous stakeholders that retail users prefer MeCl2 products because they are the most effective products.

2. EPA's own information corroborates Barr's 2015 analysis.

Despite's EPA's assertions in the preamble that effective and affordable alternatives to MeCl2-based products exist, the documents and information EPA rely upon tell a different story. As noted above, EPA's Summary of Stakeholder Engagement includes numerous testimonials from users that MeCl2 products work better, and are thus preferred by customers.<sup>33</sup> The ABT Associates memorandum on alternatives to MeCl2 and NMP-based removers acknowledges that dibasic esters and caustic removers—two of the alternatives recommended by EPA—work considerably slower than MeCl2, and caustic removers are limited in use because of the potential

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<sup>32</sup> *Id.*

<sup>33</sup> *See Id.*



that they will damage wood substrates.<sup>34</sup> Additionally, a 2006 report from the Institute for Research and Technical Assistance concluded that the most “effective stripping formulations contain METH [MeCl<sub>2</sub>].”<sup>35</sup> Documents compiled by EPA following its June 2016 outreach session also support the conclusion that paint removal products containing MeCl<sub>2</sub> are the most effective products on the market. For example, a 2014 Safer Choices Campaign study measuring the efficacy of benzyl alcohol, and dimethyl glutarate and dimethyl adipate products identified concerns about the dwell time of these alternatives and stated that “workers and supervisors felt that the effectiveness of both of these products were lacking compared to MeCl<sub>2</sub> based products in every category.”<sup>36</sup>

EPA presented a PowerPoint presentation during its June 2016 outreach session with small business entities which further document the conclusion that for a number of purposes, consumers prefer MeCl<sub>2</sub> containing products.<sup>37</sup> The presentation suggests that paint removing products containing MeCl<sub>2</sub> not only clearly outperform the alternatives, but that no alternatives have been identified for use in furniture refinishing (one of the predominant consumer-use/ DIY applications involving MeCl<sub>2</sub> containing removers).<sup>38</sup>

**C. Determining the technical feasibility of alternatives requires the use of measurable methodology and use of industry-accepted standards.**

EPA’s analysis of the efficacy of alternatives to MeCl<sub>2</sub>-containing products fails to reflect any awareness of, or apply methods that consider, the industry standard for determining efficacy. Instead, many of the documents upon which EPA appears to rely in considering the feasibility of alternatives are simply conclusory, and provide little to no information about how the conclusions were reached. For example, EPA cites a 2006 study from the European Association for Safer Coating Removal as support for its conclusion that there are feasible alternatives to

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<sup>34</sup> Memorandum from Kim Wilson & Luran Masatsugu, ABT Associates, to Judith Brown, Environmental Protection Agency, Regarding DCM & NMP Paint Stripping Alternatives (May 2014), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0283&contentType=pdf>.

<sup>35</sup> Mike Morris and Katy Wolf, Institute for Research and Technical Assistance, *Methylene Chloride Consumer Product Paint Strippers: Low-VOC, Low Toxicity Alternatives* (May 2006), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0217&contentType=pdf>.

<sup>36</sup> Jeremy Sosman and Erika Meza, *Toxic Paint Removers: Safer Choices Campaign* (Oct. 15, 2014), <http://aoec.org/ohip/wp-content/uploads/2014/08/Final-Report-San-Francisco.-Jeremy-Sosman-Erika-Meza.pdf> (emphasis added).

<sup>37</sup> Small Business Advocacy Review Panel, *Final Report on EPA’s Planned Proposed Rule, Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers*, (Sept. 23, 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0248&attachmentNumber=1&contentType=pdf>, at Appendix A.

<sup>38</sup> *Id.*



MeCl<sub>2</sub>-containing strippers.<sup>39</sup> The document referenced by EPA appears to be a 4 slide PowerPoint presentation made available on an anti-MeCl<sub>2</sub> chat forum which contains virtually no explanation of the materials and methods used in this “study”, even omitting basic details about the chemical make-up of the MeCl<sub>2</sub>-alternatives, the number of layers of coating present on the tested material, and the condition of the substrate following coating removal. Additionally, this study examined the effectiveness of coating removers over an 18-hour timeframe, far exceeding the 15-minute timeframe recommended by the ASTM standard.<sup>40</sup> Despite the lack of transparency with respect to the methodology used in this study, and its reliance on a non-standard timeframe in measuring efficacy, EPA accepted its conclusion at face value as support for its conclusion that there are feasible alternatives to MeCl<sub>2</sub>-based products.

1. *The industry standard for measuring the efficacy of coating removers is ASTM D6189-97, which establishes a “Standard Practice for Evaluating the Efficiency of Chemical Removers for Organic Coatings.”*

The ASTM standard outlines a procedure for measuring the efficacy of paint and coating removers. Barr relied on an enhanced version of this standard in conducting its 2017 efficacy analysis which tested multiple surfaces and coating types on multi-layered aged surfaces. However EPA failed to even mention the ASTM standard or the 2015 Barr report in its Alternative Analysis. Moreover, it appears that none of the studies and reports upon which EPA relies in its Alternatives Analysis explicitly followed this same standard—or a modified version of this standard—in reaching conclusions about the efficacy of alternatives to MeCl<sub>2</sub>-containing products. For example, the 2006 IRTK study reports many results and observations based on qualitative observations (e.g., “as acceptable” and “about twice as much” and “a little cleaner and worked a little faster than”) and employed methods that are unlikely to be repeatable or measurable given the irregular choice of articles to be treated, which were of variable ages, origins and physical conditions. Incredibly, EPA relies on this report to conclude that all formulations using benzyl alcohols will require “half” of the amount of stripper needed to achieve the equivalent outcome as MeCl<sub>2</sub>-based products.<sup>41</sup> EPA’s choice to rely on the IRTK study -- which does not use ASTM methods and does not rely on any reproducible quantitative metrics -- while ignoring the Barr Reports violates EPA’s obligation under Section 26 of TSCA to use the “best available science.”

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<sup>39</sup> See 82 Fed. Reg. at 7485, citing Reinhold Ruhl, *Comparison Test on the Stripping Performance, Effectiveness and Speed on Different Coating Types between DCM and DCM-free Paint Strippers*, Forum “Paint Stripping Agents” - Brussels (Nov. 1, 2005), [http://www.eascr.com/documents/2005.11.14BauBG\\_EUForum.Ruehl.pdf](http://www.eascr.com/documents/2005.11.14BauBG_EUForum.Ruehl.pdf).

<sup>40</sup> ASTM International, *Standard Practice for Evaluating the Efficiency of Chemical Removers for Organic Coatings*, D6189 - 97 (Reapproved 2014).

<sup>41</sup> Mike Morris and Katy Wolf, Institute for Research and Technical Assistance, *Methylene Chloride Consumer Product Paint Strippers: Low-VOC, Low Toxicity Alternatives* (May 2006), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0217&contentType=pdf>.



Significantly, the only document reviewed by EPA in its preparation of this rulemaking that *does* reflect a consideration of the ASTM D6189-97 standard led EPA to conclude that alternatives to MeCl<sub>2</sub>-containing products have “technical limitations,” and provided the basis for EPA to propose a 10-year exemption for uses of MeCl<sub>2</sub>-containing products for critical national security purposes.<sup>42</sup> This document, “Performance Evaluation of Hap-Free Paint Strippers vs. Methylene-Chloride-Based Strippers for Removing Army Chemical Agent Resistant Coatings,” measured the efficacy of MeCl<sub>2</sub>-containing paint strippers against the efficacy of NMP, hydrogen peroxide, and benzyl alcohol-based products when stripping Army-specification chemical agent resistant coatings (CARCs) from aluminum alloy and steel.<sup>43</sup> The report identified the benzyl alcohol-based products as the most effective alternative to MeCl<sub>2</sub>-based products, but warned that the use of these products on high-strength steels could lead to embrittlement.<sup>44</sup> This report also identified a number of CARCs for which removal using alternatives to MeCl<sub>2</sub> was less effective or completely ineffective when compared to using MeCl<sub>2</sub>-based products.<sup>45</sup>

2. *More recent data corroborate the information on technical feasibility previously made available to EPA.*

In 2017, Barr completed an update to its 2015 analysis using an enhanced version of the ASTM D6189-97 standard. The 2017 Report’s results validate Barr’s findings in the 2015 report and confirm that the limitations of alternatives to MeCl<sub>2</sub>-based products are not confined to military-grade, chemical agent-resistant paints. This analysis compared the effectiveness of MeCl<sub>2</sub>-based removers to 31 alternative removers in removing alkyd, 2-part epoxy paint, and OEM automotive coatings.<sup>46</sup> The criteria used to evaluate the effectiveness of the removers were the speed of removal and the number of coats removed. Barr’s analysis examined a wide variety of chemical-based alternative removers, including removers containing dibasic esters and benzyl alcohol.<sup>47</sup> The results of Barr’s analysis show that MeCl<sub>2</sub>-based removers were able to remove alkyd and epoxy paint faster and more effectively than the alternative removers. For example, an MeCl<sub>2</sub>-based paint remover was the only product able to remove 5 layers of a year-old alkyd paint within 15 minutes.<sup>48</sup> Alternative removers took a minimum of one hour, and up to 24

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<sup>42</sup> 82 Fed. Reg. at 7490 (Jan. 19, 2017).

<sup>43</sup> John Kelley & Thomas Considine, Army Research Laboratory, *Performance Evaluation of Hap-Free Paint Strippers vs. Methylene-Chloride-Based Strippers for Removing Army Chemical Agent Resistant Coating (CARC)* (June 2006), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0214&contentType=pdf>.

<sup>44</sup> *Id.* at 12.

<sup>45</sup> *Id.* at 12-13 (“none of the HAP-free strippers tested proved to be even slightly effective at removing the MIL-DTL-64159 Type I CARC.”); (“Several of the HAP-free strippers were successful at removing at least some portion of the top layer of the MIL-C-46168, but were not able to penetrate below that with only one application.”).

<sup>46</sup> 2017 W.M. Barr Report at 2.

<sup>47</sup> *Id.* at Table 2.

<sup>48</sup> *Id.* at Table 5.



hours, to accomplish the same result.<sup>49</sup> Additionally, MeCl<sub>2</sub>-based paint removers were the only products able to remove three layers of an OEM automotive coating within 15 minutes.<sup>50</sup> Of the alternatives to MeCl<sub>2</sub> that have been considered and reported on by EPA, only ATM was able to remove any of the OEM automotive coatings. These results provide a quantitative basis, consistent with ASTM methods, to conclude that none of the 31 alternative solvents tested in Barr's analysis were technically feasible alternatives to methylene chloride.

**D. Economically feasible alternatives to MeCl<sub>2</sub>-containing paint removers do not exist.**

EPA's analysis also overstates the availability of economically feasible alternatives to MeCl<sub>2</sub>-based products.<sup>51</sup> The cost of alternatives can greatly fluctuate with supply conditions. EPA acknowledged that two of the alternatives it considers to be plausible alternatives—benzyl alcohol and dibasic esters—are at least 25% more expensive than MeCl<sub>2</sub>.<sup>52</sup> Concerns about the cost of benzyl alcohol are also prevalent in documents referenced but apparently ignored by EPA. An excerpt of the 2001 Joint Service Pollution Prevention Opportunity Handbook stated that, "the cost difference between benzyl alcohol and methylene chloride strippers can be significant."<sup>53</sup> More recently, a 2015 memorandum from the Institute for Research and Technical Assistance confirmed that cost remains a barrier to the adoption of benzyl alcohol in the airplane refinishing industry.<sup>54</sup>

Ramboll Environ's analysis confirmed the existence of a significant cost discrepancy between MeCl<sub>2</sub>-based products and benzyl alcohol-based products, as well as a less significant, but nonetheless relevant discrepancy between the cost of MeCl<sub>2</sub>-based products and other alternative products. This analysis—based on consumer price data from May 2017—found that while the price of methylene chloride-based products averages around \$20/unit, the average price of a

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<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at Table 3.

<sup>51</sup> Barr is enclosing a report prepared by the economist, Mark Rockel, of Ramboll Environ, that reviews and offers observations on the numerous deficiencies of EPA's Economic Analysis. Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017), attached hereto as Exhibit 6.

<sup>52</sup> EPA, Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal, (Jan. 9, 2017), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0270&contentType=pdf>, at 4-9 - 4-10.

<sup>53</sup> *Benzyl Alcohol Strippers*, Joint Service Pollution Prevention Opportunity Handbook, (2001), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0065>.

<sup>54</sup> Memorandum from Katy Wolf, IRTA, to Albert Acquaye, Abt Associates, Regarding Evaluation of Paint Stripping Alternative: Task 2 (Oct. 1, 2015), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0144&contentType=pdf>.

comparable product containing benzyl alcohol averages over \$70/unit.<sup>55</sup> Similarly, other alternative (non-MeCl<sub>2</sub>) paint removal products cost an average of \$50/unit.<sup>56</sup> The conclusions of Ramboll Environ's analysis are reinforced by cost data collected by Barr. The cost data in the Barr 2017 Report also show an average cost-per-gallon of \$20 for MeCl<sub>2</sub>-containing products, and significantly higher costs per gallon for benzyl alcohol-based and other alternative paint remover products: \$70/gallon and slightly more than \$50/ gallon, respectively.<sup>57</sup> The data collected by Ramboll Environ and Barr therefore suggest that EPA's assumptions about comparative costs do not reflect a careful, national, market-based survey.

1. EPA's analysis failed to effectively consider other costs associated with alternatives to MeCl<sub>2</sub>-containing removers.

EPA's analysis does not take into consideration that less effective products require more time to complete the same stripping project when compared to MeCl<sub>2</sub> products. ATM-based paint removers are estimated by EPA -- incorrectly -- to cost approximately the same as MeCl<sub>2</sub>-based removers, but are less effective and will not remove chemically-resistant coatings. Additionally, benzyl alcohol-based products are more expensive than MeCl<sub>2</sub>-based products, and also are less effective, and in some cases completely ineffective, against chemically-resistant paints when compared to MeCl<sub>2</sub>-containing removers.<sup>58</sup> EPA incorrectly, and without any quantifiable support, assumes the alternative removers work as rapidly as, or require only slightly longer periods of time to work, than MeCl<sub>2</sub>. EPA assigns value to this small estimated difference based on assumptions about additional wages for laborers and the costs of lost "leisure time" for consumer "do-it-yourself" users. Yet the Barr data and other reports in the open literature substantiate that the effectiveness time for competing remover products can be measured in increments spanning additional hours and in some cases days, rather than mere minutes. Because EPA's cost estimate fails to recognize the "efficacy gap" between MeCl<sub>2</sub>-based products and alternative products, EPA understates the costs it does consider, such as lost leisure time, and the Agency also fails entirely to consider other costs, such as the greater amount of alternative product needed to achieve the same result, and the cost consequences of the health and safety impacts of the alternative products, discussed in greater detail below.

2. EPA's analysis erroneously assumes that the same quantity of alternative products would be needed to remove the same volume of paint.

EPA's analysis generally presumes -- without explanation and in the face of countervailing evidence -- that alternative products and MeCl<sub>2</sub> products will achieve equivalent results using the same quantity of material. As is discussed above, the Barr study and other studies

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<sup>55</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at Fig. 3.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at Figs. 2 - 3 (citing 2017 Barr Report at Table 4).

<sup>58</sup> See 2015 and 2017 Barr Reports.





demonstrate that this is not the case. Moreover, in certain instances, EPA assumes only half the quantity of benzyl alcohol-based materials will be required to obtain the same rate of paint removal as MeCl<sub>2</sub>. This conclusion seems to be drawn from the 2006 IRTK evaluation of alternatives which, as described above, contains no measured values for the comparative quantities used and reflects various qualitative assessments from volunteers without reference to industry standards and methods. Similarly, the Agency's economic analysis relies on these and other assumptions without any consideration of Barr's more data-driven comparative assessment of the efficacy of the two classes of removers. These assumptions, as EPA itself acknowledges, are often based on a lack of data.<sup>59</sup>

Documents provided to EPA by Barr, and certain reports from EPA's own contractors, should have provided sufficient basis for EPA staff to question such assumptions in its Economic Analysis. For example, a 2014 memorandum from ABT Associates to EPA states that one of the alternatives recommended by EPA—dibastic ethers—sometimes requires the use of multiple applications to remove coatings, adding to the increased costs of using this alternative.<sup>60</sup> Additionally, following a meta-analysis of the effectiveness of substitutes for MeCl<sub>2</sub> and NMP, Ramboll Environ concluded that "EPA substitutes for MeCl<sub>2</sub> and NMP are not as effective [and] are often not suitable for user needs."<sup>61</sup>

3. EPA failed to consider the Barr 2015 Report and must consider the Barr 2017 Report assessing the comparative costs attributable to an increase in the required dwell time and increased number of applications needed for use of alternative products.

As discussed above, the Barr 2015 and 2017 studies demonstrate that MeCl<sub>2</sub> is the only chemical-based removal method available that can strip alkyd paint, epoxy paint, and automotive coatings proficiently and economically.<sup>62</sup> In particular, the 2017 Barr Report provides a comparative analysis of the prices of alternative products and demonstrates that MeCl<sub>2</sub> products are less expensive than alternative products. Moreover, alternative products take far longer—up to 24 hours—to accomplish the same result as MeCl<sub>2</sub>-based products (if they do at all).<sup>63</sup> Accordingly, users will need to use a greater quantity of alternative products to achieve a result comparable to the result achieved using an MeCl<sub>2</sub> product, further increasing the actual costs of

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<sup>59</sup> EPA, Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal, (Jan. 9, 2017) at 4-28.

<sup>60</sup> Memorandum from Kim Wilson & Luran Masatsugu, ABT Associates, to Judith Brown, Environmental Protection Agency, Regarding DCM & NMP Paint Stripping Alternatives (May 2014), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0283&contentType=pdf>.

<sup>61</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 13.

<sup>62</sup> *Id.* at 14-15; see also 2015 and 2017 Barr Reports.

<sup>63</sup> 2017 Barr Report at Table 4.

using alternative products.<sup>64</sup> It is inappropriate and a violation of its Section 26 obligations for EPA to ignore the information timely provided by Barr and to fail to give it the appropriate weight when considering evidence pertinent to the economic feasibility of alternatives, especially when the Barr 2015 and 2017 Reports directly contradict the Agency's conclusions.

4. EPA's analysis of the economic feasibility of alternatives is flawed because of the Agency's failure to consider the cost of capital equipment for non-chemical removal methods.

EPA's economic analysis assumes that those companies which do not already own the capital equipment required for non-chemical removal processes like laser ablation and power-washing will not purchase that equipment if they are no longer able to use MeCl<sub>2</sub>-based products.<sup>65</sup> This conclusion implies that all current users of MeCl<sub>2</sub>-based removers would be able to, and would choose to, switch to other chemical removers. However, given that the chemical substitutes for MeCl<sub>2</sub> are far less effective than MeCl<sub>2</sub> for certain applications, some current users of retail use MeCl<sub>2</sub> products (for example, small business residential remodelers) may be forced to switch to non-chemical removers, and therefore to purchase expensive capital equipment, in order to continue their operations.<sup>66</sup> By failing to consider the costs of purchasing this equipment, EPA has unfairly underestimated the cost of this rule, especially to small businesses.<sup>67</sup>

5. EPA's analysis fails to adequately consider certain indirect costs associated with the use of MeCl<sub>2</sub> alternatives.

EPA failed to consider certain indirect costs when assessing the economic feasibility of alternatives to MeCl<sub>2</sub>-based paint strippers. For example, benzyl alcohol-based products produce about twice the amount of hazardous waste during stripping as MeCl<sub>2</sub>-based products, adding to the cost of using this alternative.<sup>68</sup> Additionally, EPA's analysis did not include the knowledge costs involved with transitioning to MeCl<sub>2</sub> alternatives. A European Union report by RPA states that, if MeCl<sub>2</sub> were to be prohibited, current users of MeCl<sub>2</sub>-based products would have to undertake more thorough assessments of their stripping projects in the future to determine which MeCl<sub>2</sub> alternative best fits the requirements of each project.<sup>69</sup> EPA's analysis

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<sup>64</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 15.

<sup>65</sup> EPA, *Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal*, (Jan. 9, 2017), at 4-10.

<sup>66</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 15.

<sup>67</sup> *Id.* at 31-32 (outlining EPA's failure to identify and consider alternatives that would minimize the impact of this rulemaking on small businesses).

<sup>68</sup> *Id.* at 7 (citing Memorandum from Kim Wilson & Lauran Masatsugu, ABT Associates, to Judith Brown, Environmental Protection Agency, Regarding DCM & NMP Paint Stripping Alternatives (May 2014)).

<sup>69</sup> *Id.* at 20 (citing Risk & Policy Analyst Limited, *Impact of Potential Restrictions on the Marketing and Use of Dichloromethane in Paint Strippers*, prepared for the European Commission Directorate-General Enterprise and

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did not seek to quantify, or even consider, the cost of the additional knowledge and time required to undertake these assessments.<sup>70</sup>

**E. Available alternatives do not benefit health, may increase risk to consumers, and alternatives' effects on the environment have not been compared.**

**1. EPA failed to examine readily available information on reported consumer incidents resulting from use of alternative (non-MeCl<sub>2</sub>) paint stripper products.**

The report prepared by Dr. Kingston of Safety, Science & Toxicology Associates LLC, as described in greater depth above, analyzes the wealth of data from poison control centers -- routinely consulted by EPA in other rulemakings -- which demonstrate that consumer exposures to MeCl<sub>2</sub>-containing paint strippers have been steadily declining since 2003<sup>71</sup> while similar exposures involving non-MeCl<sub>2</sub> alternative strippers have not similarly declined<sup>72</sup>. Dr. Kingston's report finds that reports to poison control centers of exposure incidents involving non-MeCl<sub>2</sub> products have in fact considerably exceeded the number of reported MeCl<sub>2</sub> events during the most recent 5-year period reported.<sup>73</sup> The difference in the number of reported events is even more dramatic considering the relative market shares for such products.

These data contradict the core concern expressed by the Agency for residential consumer exposures during use of retail paint strippers. In a hypothetical future market where EPA's proposed rule has become effective, and where MeCl<sub>2</sub> products are no longer available to consumers, the consumer market will logically shift to non-MeCl<sub>2</sub> products. But the Kingston Report shows that such a market shift -- the very result that EPA seeks -- will increase the number of consumer exposure incidents, since non-MeCl<sub>2</sub> product incidents impacting consumers are greater than those involving MeCl<sub>2</sub> products. The disparity between the number of exposure incidents caused by MeCl<sub>2</sub> products and the number of exposure incidents caused by non-MeCl<sub>2</sub> products is even more pronounced in light of the much larger market share of MeCl<sub>2</sub> products. As is discussed above, EPA did not conduct its own analysis of AAPCC data, and even the flawed analysis conducted by CPI that the Agency did rely upon contained no analysis comparing MeCl<sub>2</sub> incident data to incident data of alternative products. Accordingly, EPA has failed to meet its obligation under Section 26 of TSCA to use the best available science in undertaking this rulemaking.

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*Industry* (April 2007), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0057&contentType=pdf>).

<sup>70</sup> *Id.*

<sup>71</sup> Dr. Richard Kingston, Safety, Science & Toxicology Associates, *Paint Stripping Agents & Adverse Event Data Trends* (May 2017) at 7-8.

<sup>72</sup> *Id.* at 16.

<sup>73</sup> *Id.* at Fig. 10.

2. *Additional shortcomings of EPA's assessment of consumer risks from alternative strippers.*

Although overlooking the available information from national poison control center data, EPA prepared an “assessment” of toxicity and exposure potentials for individual compounds selected as key ingredients for alternative products not containing MeCl<sub>2</sub>.<sup>74</sup> These compounds were: benzyl alcohol, dibasic esters (dimethyl succinate, dimethyl glutarate and dimethyl adipate); ATM; and caustic chemicals (calcium hydroxide or magnesium hydroxide).<sup>75</sup> EPA’s assessment relied on hazard profiles that the Agency generated for selected alternatives, and its estimates for the comparative exposure potential of the alternatives.<sup>76</sup> However, much of the toxicity data presented for several compounds were not germane to the kinds of limited, episodic and intermittent exposures consumer users and residential remodeling and painting contractors experience when using paint removers.<sup>77</sup> Additionally, EPA relied on data from studies involving oral routes of administration and repeated dose toxicity studies using exposure pathways not relevant to potential inhalation and dermal contacts more likely during consumer and residential uses of these compounds for paint stripping.<sup>78</sup>

In his report, Dr. Lumpkin performed a more quantitative assessment of the potential risks from equivalent exposures to alternative paint stripping compounds likely to be experienced during consumer residential uses of retail paint stripping products. CTEH reviewed the toxicology data for the 14 key alternative compounds that EPA identified, as well as for mechanical sanding particulates. Unlike EPA, CTEH also conducted consumer-use simulation modeling for 8 of the alternative compounds to provide exposure estimates for performance-equivalent uses of the alternatives that are directly comparable to scenarios used by EPA to determine risks to consumers using MeCl<sub>2</sub>.<sup>79</sup> Further, CTEH used comparative paint stripper performance data provided by Barr to determine plausible performance-equivalencies for applied amounts and residence (dwell) times for each alternative compound.<sup>80</sup> The benchmark MOEs for the alternative compounds derived by CTEH reasonably account for data uncertainty and calculated risk values. CTEH’s risk calculations, using EPA’s methodology, show that only one class of stripper compounds (dibasic esters) create risks to paint stripper users that EPA would likely

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<sup>74</sup> Analysis Report of Chemical Alternatives for Use of Methylene Chloride- and N-Methylpyrrolidone-based Paint Removers: Hazard and Exposure Concerns, [RIN 2070-AK07], November 7, 2016

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> Michael H. Lumpkin, Center for Toxicology & Environmental Health, *Comments on the Health Risk Basis for U.S. Environmental Protection Agency’s Proposed Regulation of Certain Uses of Methylene Chloride and N-Methylpyrrolidone Under TSCA 6(a)* (May 2017) at 13.

<sup>80</sup> *Id.*



deem to be reasonable.<sup>81</sup> However, as demonstrated by Barr's 2015 and 2017 Reports, the performance characteristics of dibasic ester products render them both technologically and economically infeasible for consumer users.

3. EPA did not seriously consider flammability concerns for consumer DIY users.

The flammability risk of alternative products has been made known to EPA through numerous sources, and is well documented in this rulemaking. For example, the CPSC in June of 2016 advised EPA that:

“Changes to the availability of this product [MeCl<sub>2</sub>-containing paint removers] for consumer use and the use of alternatives that may present different acute hazards must be carefully considered. The use of more flammable coating removers may present the potential for a greater fire risk, loss of furnishings, and risk of injury to consumers.”<sup>82</sup>

However, EPA did not assess the comparative flammability risks of MeCl<sub>2</sub> products and alternative products, dismissing such an assessment as “impracticable.”<sup>83</sup> Rather, EPA asserted that since paint remover products contain multiple chemicals of varying flammability, it could not forecast whether the products that might replace MeCl<sub>2</sub> products would be more or less flammable than MeCl<sub>2</sub> products.<sup>84</sup>

EPA's rationale for not investigating flammability does not stand up to serious scrutiny. Barr retained Exponent Inc. to conduct a flammability analysis comparing MeCl<sub>2</sub> to the alternative products<sup>85</sup>. Exponent analyzed the active ingredients used in paint remover products according to several well-established metrics of flammability. Exponent also analyzed actual products for their composite fire risk. As documented in the EPA Paint Remover Flammability Analysis report prepared by Exponent, several of the 14 key ingredients identified by EPA are highly flammable materials, creating a physical health hazard that is not present for methylene chloride. Of the 14 ingredients Exponent analyzed, MeCl<sub>2</sub> has one of the lowest Flammability Hazard Ratings under the National Fire Protection Association standards. Exponent also analyzed the replacement products in their totality, considering that each product is a composite of several

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<sup>81</sup> *Id.* at 34.

<sup>82</sup> Letter from Patricia H. Adkins, Consumer Product Safety Commission, to James J. Jones, Environmental Protection Agency (June 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0154&contentType=pdf>, at 3.

<sup>83</sup> 82 Fed. Reg. at 7,487 (Jan. 19, 2017).

<sup>84</sup> *Id.*

<sup>85</sup> R. Tom Long & Y. Pock Utiskul, Exponent, *EPA Paint Remover Flammability Analysis* (May 2017), attached hereto as Exhibit 7.



chemicals, and also accounting for the increased dwell time attributable to less effective alternative consumer products. Exponent concluded that MeCl<sub>2</sub> products present lower flammability risks than do ATM products, which, according to the Barr 2015 and 2017 Reports are the most effective alternative consumer-use paint stripper products. Thus, the consumer products most likely to replace MeCl<sub>2</sub> products due to their greater effectiveness are in fact greater flammability risks than are MeCl<sub>2</sub> consumer-use paint strippers.<sup>86</sup>

EPA was advised by its sister agency CPSC that banning consumer use of MeCl<sub>2</sub> paint strippers could increase use of more flammable alternative products. The Agency did not act on this warning. EPA could have conducted a study similar to that conducted by Exponent to determine for itself the extent of the comparative flammability risk of different paint remover products; it chose not to do so. The Agency asserted that such a study was “impracticable,” when the Exponent study demonstrates that such a study can be performed without undue cost or time. The Exponent study itself demonstrates that the alternative products pose a greater fire risk than do MeCl<sub>2</sub>-based products. Accordingly, EPA has failed to meet its obligations under Section 26 of TSCA to use the best available by science by failing to conduct a flammability study, by failing to heed the warning of CPSC, and -- if it chooses to promulgate this rule -- by proceeding with a rulemaking that fails to account for the documented increase in flammability risk posed by alternative products.

4. EPA has not reasonably considered consumer-use exposures and other risks from available non-MeCl<sub>2</sub> products.

As the reports from Dr. Kingston, CTEH, and Exponent demonstrate, EPA has not shown that the weight of the scientific evidence supports a conclusion that non-MeCl<sub>2</sub> alternative strippers present fewer risks to consumer users or small business contractors than MeCl<sub>2</sub> products. EPA must conduct a more robust comparison of the incident data, relative toxicity, comparative flammability and efficacies of MeCl<sub>2</sub> and the alternative paint stripping compounds before the Agency makes a final determination about the comparative safety, as well as the technical and economic viability, of the alternatives to MeCl<sub>2</sub>. Additionally, after conducting these comparisons, EPA must incorporate their results into its cost-benefit analysis, which the Agency itself admits that it has failed to do for the current rulemaking with respect to health effects.<sup>87</sup>

5. EPA has not critically evaluated the comparative environmental impacts of MeCl<sub>2</sub> paint strippers when compared to alternatives.

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<sup>86</sup> Id. at 28-30, 38.

<sup>87</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 18 (citing EPA, *Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal*, (Jan. 9, 2017), at xi).



The Agency's NPRM correctly notes that MeCl<sub>2</sub> is not an ozone-depleting substance, and is listed as "acceptable" under the Agency's Significant New Alternatives Policy (SNAP) program for certain uses. Moreover, MeCl<sub>2</sub> is not considered to be a volatile organic compound (VOC) on the basis of an exemption for which the substance qualifies.<sup>88</sup> Additionally, MeCl<sub>2</sub> is considered to be biodegradable over a range of rates and environmental conditions and its bioaccumulation potential is low.<sup>89</sup>

In consideration of the environmental effects of NMP, EPA notes in the preamble to the proposed rule that would ultimately prohibit NMP's use in retail consumer-use products, "[b]ased on NMP's low persistence, low bioaccumulation, and low hazard for environmental toxicity, the magnitude of potential environmental impacts on ecological receptors are judged to be low for the environmental releases associated with the use of NMP in paint and coating removal." Further, no Global Warming Potential (GWP) has been developed for NMP "because of its very short atmospheric lifetime. Based on its very short half-life, its GWP is expected to be very low." EPA has determined that, "NMP is not an ozone-depleting substance" and (like MeCl<sub>2</sub>) is listed as "acceptable" under SNAP program for certain uses. Also like MeCl<sub>2</sub>, EPA concludes that "NMP is not a VOC".<sup>90</sup>

EPA considers benzyl alcohol containing strippers to be likely replacements for the prohibited MeCl<sub>2</sub> and NMP strippers. However, benzyl alcohol is a VOC, and so its use may not be appropriate in areas designated as Non-Attainment Areas under the Clean Air Act.

Because EPA's proposed regulatory action will, by the Agency's own admission, increase the level of use of alternative chemical paint stripper products in the retail consumer sector, it is incumbent upon the Agency pursuant to Section 6(c) of TSCA to perform a comprehensive, technically competent side-by-side comparison of alternative chemistries to attempt to determine if the move away from MeCl<sub>2</sub> and NMP in retail paint strippers will be truly beneficial for human health and the environment.

**F. EPA did not satisfy its Section 6 duty to adequately assess costs and benefits and failed to satisfy the standards of OMB's requirements and EPA's own guidance regarding economic analyses.**

EPA is required for any rule promulgated pursuant to TSCA Section 6 to consider "the reasonably ascertainable economic consequences of the rule" including "the costs and benefits of the proposed regulatory action" and its alternatives and the cost effectiveness of the proposed

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<sup>88</sup> 82 Fed. Reg. 7469 (Jan. 19, 2017)

<sup>89</sup> *Id.*

<sup>90</sup> 82 Fed. Reg. at 7,499 (Jan. 19, 2017).



regulatory action and its alternatives.<sup>91</sup> In addition to the requirements of TSCA Section 6(c), EPA is required under applicable Executive Orders to conduct a thorough analysis of the costs and benefits of any proposed regulation. Executive Order 12866 requires agencies to “assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”<sup>92</sup> Executive Order 13,563 further states that agencies, in proposing regulations, must “select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).”<sup>93</sup> More recently, Executive Order 13777 requires all Agencies to establish a Regulatory Reform Task Force to make recommendations as to the “repeal, replacement or modification” for regulations, that, among other things, “impose costs that exceed benefits.”<sup>94</sup>

As previously discussed, Barr is submitting a report prepared by Ramboll Environ providing an economic analysis of the Proposed Rule.<sup>95</sup> The Ramboll Report concludes that EPA has failed to meet the requirements of TSCA and the applicable Executive Orders mandating a thorough economic analysis of the Proposed Rule, as well as the Agency’s own Guidance for Implementing Executive Orders Pertinent to Economic and Regulatory Impact Analysis.

1. EPA’s economic analysis shows that costs of the Proposed Rule outweigh the Rule’s benefits.

EPA provided a cost benefit analysis as required by OMB Circular A-4. The results of that analysis show annualized monetized benefits at \$13.8 - \$14.6 million, and annualized monetized costs of the Proposed Rule at \$116-\$124 million.<sup>96</sup> Thus, by EPA’s own analysis, the benefits of the rule are dwarfed by its costs. As a threshold matter, a rulemaking for which the Agency’s own analysis shows that costs exceed benefits does not satisfy Executive Order 13777, and such a rulemaking lacks substantial evidence that the benefits of the rule exceed the costs. The discrepancy of costs compared with benefits is intensified by the fact that EPA’s cost estimates are likely too low, as discussed in further detail below.

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<sup>91</sup> See 15 U.S.C. § 2605 (c)(2)(A)(iv).

<sup>92</sup> Exec. Order No. 12,866 § 1(b)(6), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

<sup>93</sup> See Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 21, 2011).

<sup>94</sup> Exec. Order. No. 13,777 § 3(d)(iii), 82 Fed. Reg. 12,285 (March 1, 2017).

<sup>95</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017).

<sup>96</sup> See Reg. Plan Costs & Benefits Table for Regulation of Methylene Chloride and NMP Use in Paint Removers Under TSCA § 6(a); Second Co-Proposed NMP Option (Jan. 2017), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0288&attachmentNumber=8&contentType=pdf>.



Additionally, EPA's cost benefit analysis does not comply with Executive Order 12866, which requires the Agency, among other things, to consider alternatives to a regulation that will reduce the regulation's impact on small businesses.<sup>97</sup> As discussed in further detail below, EPA did not adequately consider alternatives such as labeling that would mitigate risk without imposing such a significant burden on small businesses and other users of MeCl<sub>2</sub>-based paint removal products.<sup>98</sup> This failure to adequately consider alternative risk mitigation approaches is amplified by other errors and oversights in EPA's cost benefit analysis—namely its failure to consider the risks posed by non-MeCl<sub>2</sub> products in calculating net benefits and its underestimation of the costs of alternatives to MeCl<sub>2</sub>-based products.<sup>99</sup>

2. EPA has failed to follow Its own guidance for economic analyses.

EPA is required under its own guidance for conducting economic analyses to consider a range of factors, including the costs to businesses of abandoning MeCl<sub>2</sub> and NMP product lines.<sup>100</sup> EPA did not consider potential lost profits, which is particularly impactful to small businesses that operate on a small profit margin. By failing to do so, the Agency's economic analysis has devalued the obvious impact the proposed rule would have on businesses (in particular small businesses) that will need to completely abandon entire paint removal product lines, which EPA mischaracterizes merely as "product reformulation."

Relying on sales data from Barr, the Ramboll report estimates that by forcing a shift to alternative paint strippers, the Proposed Rule will prompt a profit loss of over \$160 million annually in North America due to loss of sales of products containing MeCl<sub>2</sub> and NMP products.<sup>101</sup> While some of these lost profits may be compensated by sales of other products, EPA has put forth no analysis with respect to the purchase of alternative products. The capacity of Barr and other stakeholders to compensate for these lost profits would also be dependent on their ability to substitute MeCl<sub>2</sub> in their existing products with alternative chemical substances<sup>102</sup>—an ability which has been called into question by Barr's 2015 and 2017 reports. These costs were not considered by EPA in its cost analysis.

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<sup>97</sup> Exec. Order No. 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

<sup>98</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 34-35.

<sup>99</sup> *Id.*

<sup>100</sup> National Center for Environmental Economics, Environmental Protection Agency, *Guidelines for Preparing Economic Analyses* (Updated May 2014), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0114&contentType=pdf>.

<sup>101</sup> Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 29.

<sup>102</sup> *Id.*

EPA also erroneously concluded that this rulemaking would result in cost savings to industrial users—a conclusion that allowed EPA to show a net benefit from the rulemaking in certain scenarios.<sup>103</sup> EPA offers no explanation for how these cost savings would be generated, or how these savings are distinguishable from those that already exist as a result of the competitive paint stripper market.<sup>104</sup> EPA’s unsupported conclusion does not satisfy the Agency’s obligations under its own regulatory guidance<sup>105</sup> or its obligation under Executive Order 12866: to adopt a regulation “only upon a reasoned determination that the benefits of the intended regulation justify its costs.”<sup>106</sup>

3. EPA’s economic analysis did not consider the increased expenses and cost impact of increased health and flammability risks from the alternative products.

As documented in the Barr Reports and multiple other sources in the Agency’s docket, alternative paint stripper products are generally less effective than MeCl<sub>2</sub>-containing products (see section II, above), and accordingly require more time to achieve results comparable to the results achieved using MeCl<sub>2</sub>-containing products. EPA’s cost analysis failed to consider: (i) the increased cost to consumers of having to use more of a less effective product, or (ii) the increased health and environmental impacts of using greater quantities of these products. For example, EPA did not consider that costs of the use of products containing benzyl alcohol, the product EPA believes most likely to be the substitute for most uses of MeCl<sub>2</sub>. Benzyl alcohol is an eye, nose throat, skin and lung irritant and, as discussed above, generates about twice the quantity of hazardous waste as MeCl<sub>2</sub>-based products. Additionally, as noted previously, EPA did not effectively evaluate the comparative flammability of the retail consumer-use paint stripper formulations, a concern noted by the CPSC.<sup>107</sup> Substitute products containing ATM are carcinogenic, flammable and cause neurological effects and heart attacks if not used properly. Significantly, the California Department of Public Health recommends not using these products due to their health risks. As is discussed above, by simply dismissing the notion of comparative flammability risks from alternative strippers, and assuming without study that the alternatives present few risks to consumer users, EPA failed to consider the health effects of these products in its cost analysis.<sup>108</sup>

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<sup>103</sup> *Id.* at 3.

<sup>104</sup> *Id.*

<sup>105</sup> EPA’s Guidelines for Preparing Economic Analyses require it to consider social cost in its analyses, including the consideration of factors such as the potential health risks of using alternative products, and the reduced efficacy of alternative products. See Mark Rockel, Ramboll Environ, *Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (May 2017) at 2-3.

<sup>106</sup> Exec. Order No. 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

<sup>107</sup> Letter from Patricia H. Adkins, Consumer Product Safety Commission, to James J. Jones, Environmental Protection Agency (June 2016).

<sup>108</sup> 82 Fed. Reg. at 7,487 (Jan. 19, 2017).



4. EPA did not appropriately consider the costs to consumers of transitioning to contract paint stripping services.

EPA barely acknowledges, let alone analyzes, the cost to consumers who must give up DIY uses of MeCl<sub>2</sub> strippers entirely. In light of the reduced effectiveness and greater cost involved with using the alternative products, significant numbers of DIY consumers are likely to transition either to using contractors for home paint stripping projects, at a much greater cost, or to using mechanical rather than chemical methods, also entailing greater costs, leisure time, and additional health risks. This scenario was not adequately quantitatively incorporated into EPA's cost analysis.

Additionally, EPA's conclusion that this regulation would not have an overall adverse impact on the national economy<sup>109</sup> is not based on a consideration of all reasonably available information, as required under TSCA Section 26(k)<sup>110</sup>. For example, there is no indication that EPA made an effort to obtain and consider information in authoritative national publications concerning the size of the paint stripper market to assess impacts to formulators and distributors of MeCl<sub>2</sub>- and NMP-containing paint strippers.<sup>111</sup> Consequently, in its Regulatory Flexibility Analysis, EPA dramatically underestimates the number of businesses that formulate paint stripper products in the US and likewise understates the number of such enterprises that constitute small businesses.

EPA assumes, without analysis or explanation, that the Rule is justified by "market failure." That is, consumers are not obtaining adequate information about the risks of MeCl<sub>2</sub> products, and thus a rule is necessary based on the assumption that, if consumers did receive adequate information, it would lead them to not purchase these products. But EPA has provided no analysis supporting this hypothesis. In fact, the data collected by Dr. Kingston shows that the number of incidents reported to Poison Control Centers has declined significantly over the last 15 years. Mr. Hall's human factors analysis (discussed below) shows that consumers can and do follow label directions that are clear and direct. These reports collectively demonstrate that consumer users are capable of interpreting the labels and heeding warnings properly. EPA's "market failure" hypothesis is therefore unsupported by the record EPA has assembled. The available evidence more strongly indicates that consumers are fully aware of the risks, and are managing their use of the products accordingly, thus accounting for the dramatic decline in incidents.

In sum, EPA has failed to conduct a proper analysis of costs and benefits consistent with the requirements of Executive Orders 12866, 13563 and 13777. By ignoring entire categories of information EPA has also failed to comply with the requirements of TSCA Section 6 to

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<sup>109</sup> *Id.* at 7,489.

<sup>110</sup> 15 U.S.C. § 2625 (k).

<sup>111</sup> See, e.g., the QYR Chemical & Material Research Center, *2017 Market Research Report on Global Paint Remover Industry*, attached hereto as Exhibit 9. This is a readily available source updated annual by its publisher.



“consider” the “reasonably ascertainable economic consequences” of the Rule, and has failed to follow its own Agency guidance for conducting a cost analysis.

The foregoing failings, coupled with the absence of technically and economically feasible alternatives to MeCl<sub>2</sub>-containing paint removers, make clear that EPA lacks a sufficient basis to proceed with a final Section 6(a) rule that would explicitly prohibit retail sales of consumer-use retail-sized containers of MeCl<sub>2</sub>-containing paint strippers.

### **III. EPA Failed to Objectively and Credibly Review Alternative Risk Mitigation Strategies Including Enhanced Product Labeling, Product Reformulation Requirements, and Limitations on Consumer Uses of Aerosol Strippers.**

Section 6 of TSCA and the applicable Executive Orders require EPA to consider alternative regulatory strategies and their comparative benefits, costs, and economic impacts. It is apparent that more subtle, swift, and cost effective approaches to addressing risks to consumers from retail-size MeCl<sub>2</sub> and NMP paint stripper products exist. Applying the standards set forth in the amended statute, EPA should adopt a regulatory alternative that is focused on reducing unreasonable risks to reasonable levels, rather than an outright prohibition on consumer-use retail-size containers of MeCl<sub>2</sub> and NMP paint strippers. To accomplish this, EPA should implement an effective risk mitigation strategy that relies on improved labeling for retail-size consumer-use MeCl<sub>2</sub> paint strippers and enhanced risk communication to retail consumer/users and residential remodeler contractors.

#### **A. EPA is required by Section 6(c) to undertake a more comprehensive and credible analysis of regulatory alternatives.**

TSCA Section 6(c) requires EPA to consider both the costs and benefits and the cost-effectiveness of alternatives to its proposed regulatory approach. Executive Order 12866 also requires each federal agency to “identify and assess alternative forms of regulation” and to “tailor its regulations to impose the least burden on society,”<sup>112</sup> while Executive Order 13563 requires agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public<sup>113</sup>.” Executive Order 13563 specifically calls for the use of “warnings, appropriate default rules and disclosure requirements” as the kinds of alternatives that meet the need for “flexible approaches.”<sup>114</sup>

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<sup>112</sup> Exec. Order No. 12866 §§ 1(b)(7), (11), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

<sup>113</sup> See Exec. Order No. 13563 § 4, 76 Fed. Reg. 3,821 (Jan. 21, 2011).

<sup>114</sup> *Id.*



Here, EPA conducted a flawed and superficial analysis of the use of labels and warnings as a regulatory alternative and, without a proper basis for doing so, simply rejected this alternative.<sup>115</sup> Barr is submitting a report by Steven Hall of ASE,<sup>116</sup> which evaluates EPA's consideration of this alternative, as well as the broader use of labels and warnings. ASE concludes that labels and warnings can be an effective strategy for addressing the risks posed by MeCl<sub>2</sub> paint removal products.

*1. EPA's review of warning literature is inconclusive as to the effectiveness of warnings for paint-removal products.*

EPA relies on its review of a compilation of label and warning studies to conclude that labels and warnings will not be effective at addressing the risks to consumers and residential users of MeCl<sub>2</sub>- and NMP-containing paint removers. However, the vast majority of literature reviewed by EPA does not address paint remover products specifically, and therefore should be accorded less weight than studies that do. For example, two publications cited in the Agency's literature review do pertain to paint remover labeling specifically,<sup>117</sup> and they, along with a related publication,<sup>118</sup> provide evidence that such labeling has the potential to affect behavior and mitigate real-world risk. For reasons that are not transparent, EPA has failed to accord the weight it reasonably should have to such studies.

On the basis of its literature review, the Agency has attempted to extrapolate from a wide variety of information about numerous other classes of products and other forms of product warnings to make a prediction about the warnings that the Agency has the authority under TSCA to prescribe for retail use MeCl<sub>2</sub> paint removers. Such predictions are inappropriate because they give less weight to studies specifically pertaining to paint stripper products. ASE identified literature reviewed by EPA that is specific to paint removers and shows that labeling can reduce actual

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<sup>115</sup> Strangely, EPA also rejects the use of labeling to address risks in the consumer context because the statute does not provide EPA with the authority to compel consumers to *comply* with label restrictions. Therefore, the Agency asserts that the preferred regulatory alternative is to completely take away consumer access to such products. Not only does this reading effectively make the terms of Section 6(a)(3) relating to labeling regulations superfluous, this reasoning also suggests that EPA *must*, under TSCA, prohibit the manufacture and processing and distribution of all consumer products that present an unreasonable risk to the user *if the product warnings are not followed*. This is an absurd reading of the Act, and the logic undermines EPA's entire pesticides program -- which largely relies on labeling to protect product users from unreasonable adverse effects. Alternatively, perhaps Congress simply intended that EPA should defer to CPSC when considering regulation of hazardous substances present in consumer product formulations.

<sup>116</sup> Steven Hall, Applied Safety & Ergonomics, *Response to EPA Analysis Regarding Methylene Chloride Paint Remover as a Potential Risk Mitigation* (May 2017).

<sup>117</sup> Abt, 1992 and Riley, 2001

<sup>118</sup> (Westat, 1987)



risk. The ASE report cites to several studies that show that label changes did impact user behavior in a way that reduced risk posed by paint stripper products.

Significantly, the literature cited by EPA also did not include evaluations of recent changes to the MeCl<sub>2</sub>-based products that Barr distributes (and the language changes that CPSC currently is considering) that contain revised warnings including, for example, a clear and specific warning not to use MeCl<sub>2</sub>-containing strippers on bathtubs. EPA's reliance on generic conclusions about the efficacy of warnings generally does not justify the specific conclusions the Agency reached with respect to the effectiveness of warning for MeCl<sub>2</sub> paint strippers. Moreover, there is considerable literature and widely accepted published standards applicable to warnings that are used and accepted in many industries and trades. However, without explanation, the many kinds of warnings and messages that the Agency could prescribe under TSCA were not carefully vetted in EPA's assessment. Thus, the weight of the evidence of the literature reviewed by EPA does not support the conclusion that adequate and updated warnings and instruction for use will not mitigate unreasonable risks to consumer users of retail paint strippers.

2. The analysis of fatality data cited by EPA indicate that warnings can be effective.

As is discussed in Section I above, the available incident data from poison control center reports show a substantially declining overall rate of reported incidents associated with MeCl<sub>2</sub> paint removal products, and within that data a declining number of significant incidents. Since these paint remover formulations have been on the market for many years, and labeling of these products has changed over time, EPA's analysis and predictions can be compared to and evaluated based on relevant field experience. To this end, as initially discussed in Section I.B, above, ASE analyzed the fatality data referenced and apparently relied upon by EPA in the proposed paint stripper regulation. ASE examined and categorized all cited fatalities to better understand the specific real-world scenarios that result in fatal MeCl<sub>2</sub> paint stripper incidents. The ASE report provides details on their methods and the data reviewed.

The EPA fatality data ASE evaluated demonstrate that the vast majority of consumer paint stripper users are capable of using the product in a way that does not result in the overwhelming neurological and cardiovascular effects which form the basis for EPA's risk concerns for consumers. Only a small number of fatalities were associated with consumer use: of 65 fatalities, three are of unknown type and three are consumer uses, with four of these unknown or consumer fatalities dating from the 1970s. To the extent that there are incidents associated with commercial use, the incidents reflect non-conformance with OSHA regulations. ASE concluded based on its review of the reports cited in the preamble to the proposed rule that recent and current documented real-world risks of fatalities from over-exposures were primarily associated with MeCl<sub>2</sub>-based paint removers used in professional bathtub refinishing activities. The data in the reports cited by EPA involving MeCl<sub>2</sub> strippers did not indicate an unreasonable risk of fatalities associated with consumer use, including with respect to consumer bystanders, children, infants, or developing fetuses. The data also suggest that risks associated with occupational use, other than bathtub stripping, have been greatly reduced.



The ASE report also concluded that additional warning and consumer education have the potential to further reduce risks. ASE proposes that the literacy issues EPA suggests are confounding label comprehension can be addressed with multi-lingual labelling and depictions (such as the “Do not use for bathtub stripping” symbol, discussed above that has been recently proposed to the CPSC and implemented recently by W.M. Barr). *See* additional discussion in III.C and D., below.

**B. Other federal programs routinely use warnings and labels to convey information and manage risk.**

EPA’s assertions about the ineffectiveness of labeling to provide information to consumers and manage risk are inconsistent with the broad application of these strategies in other federal programs, including its own. For example, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) regulates pesticides mainly through a program of mandatory labeling. EPA ensures that pesticides are used safely based on warnings and directions for use that are proposed by the applicant and approved by EPA. Applicants are required to provide specific data and studies to EPA to justify that the product, when used according to its label, is safe, effective and not harmful to the environment. Moreover, the FIFRA program is situated within EPA under the management of the same Assistant Administrator who oversees the TSCA program. Certainly, EPA has the capacity to draw upon the expertise of its personnel in the pesticide program to assist the TSCA staff in developing a labeling standard for consumer-use paint strippers.

Similarly, the EPA Safer Choice campaign (also within the same office of EPA) uses product labels to promote the use of products that are safer for families, pets and workplaces. EPA evaluates all ingredients in a product and only provides the Safer Choice label on products that do not use “problematic” chemicals. Surely, EPA would not initiate a program aimed at using consumer product labels to promote green chemistry and protection of public health and the environment if the Agency legitimately believes consumers do not read and comprehend product labels.

Particularly relevant to this rulemaking, as discussed above, the CPSC uses a system of labeling under the Federal Hazardous Substances Act (FHSA) to address risks of a variety of products used in both consumer and in occupational settings, including paint removers containing MeCl<sub>2</sub>. EPA has not suggested that CPSC’s product label standards are ineffective or require EPA regulatory action.

**C. EPA failed to consider collaboration with the Consumer Product Safety Commission to effectively address concerns for consumer users of MeCl<sub>2</sub> paint strippers.**

The CPSC is actively considering a petition voluntarily submitted by the trade association that represents Barr and other MeCl<sub>2</sub> paints stripper formulators who are seeking amendments to the



CPSC standards for labeling of such products.<sup>119</sup> The petition asks CPSC to amend and update the labeling standards the Commission codified in 1987. The petition seeks to conform the standard with Barr's current practice of discouraging uses, such as bathtub stripping, that are most associated with acute effects from use of MeCl<sub>2</sub> strippers. The front panel of current editions of Barr's MeCl<sub>2</sub> paint stripper labels specifically warns against use of the product for bathtub stripping. The potential for consumers to suffer acute effects from exposure to MeCl<sub>2</sub> strippers in small spaces was reportedly the initial focus of EPA's concern, and the Agency should support and encourage the CPSC's rapid action on the petition seeking to enhance its current Statement of Interpretation and Enforcement Policy regarding labeling of household products containing MeCl<sub>2</sub>. CPSC's rapid action will standardize industry practice and establish a baseline that is consistent with the improvements Barr has made to its own labels and that we encourage our competitors to make as well.<sup>120</sup>

**D. EPA's support of the CPSC labeling efforts is consistent with TSCA and would provide a practical approach to enhancing user awareness.**

This approach also enables EPA to address a concern the Agency identifies in the preamble to the proposed rule that it is unable to enforce consumer compliance with label standards. Supporting the CPSC effort provides a solution to this issue. In meetings with EPA, and in various written submissions, Barr has and continues to encourage EPA to work collaboratively with the CPSC and the producers of paint stripper products who share the common goal of improving risk communication and discouraging high-risk uses (such as DIY bath tub stripping). Such a collaboration could identify additional customer and user education opportunities, such as those discussed in the report submitted by Barr that was prepared by Mr. Hall of ASE.<sup>121</sup>

**E. EPA has not accounted for ASTM's development of a standard for the use of paint and coating removal products containing MeCl<sub>2</sub>, inconsistent with OMB Circular A-119.**

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<sup>119</sup> The petition submitted by the Halogenated Solvents Industry Alliance (HSIA) and was announced in a 2016 publication in the Federal Register and CPSC has solicited public comment on its consideration. 81 Fed. Reg. 60,298 (Sept. 1, 2016). The label submitted by HSIA goes beyond the language required by the 1987 precautionary language standard and stated "Do Not Use To Strip Bathtubs," with a corresponding pictogram. CPSC staff has already approved the expanded cautionary language, which formulators are using. See Halogenated Solvents Industry Alliance, *Petition to Amend the Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride Issued by the Commission Under the Federal Hazardous Substances Act* (July 2016), attached hereto as Exhibit 8.

<sup>120</sup> If during its review the CPSC staff determine additional and more explicit warnings should be provided, Barr encourages CPSC to confer directly with the petitioners.

<sup>121</sup> Steven Hall, Applied Safety & Ergonomics, *Response to EPA Analysis Regarding Methylene Chloride Paint Remover as a Potential Risk Mitigation* (May 2017).



A committee of the ASTM has begun work on a standard of labels and warnings for paint removers containing MeCl<sub>2</sub>. While this work is still in the early stages, development of a voluntary industry standard for labels and warnings on paint removal products containing MeCl<sub>2</sub> presents an opportunity for EPA to reconsider its Proposed Rule. According to OMB Circular A-119, federal agencies should seek to use voluntary consensus standards in regulatory activities in lieu of promulgating Government-specific standards.<sup>122</sup> Notably, the CPSC is required to rely on voluntary standards in lieu of its own submitted to it during the rulemaking progress if it determines that such standards will reduce or eliminate the risk of injury.<sup>123</sup> At the time EPA initiated public comment on the Proposed Rule, no ASTM process was ongoing. Now that ASTM has begun development of a voluntary standard, EPA must comply with OMB Circular A 119, as well as with the National Technology Transfer and Advancement Act, section 12(d)<sup>124</sup>, and defer any further action on the Proposed Rule until the ASTM process is complete and EPA can review the ASTM standard for labels and warnings for paint removers containing MeCl<sub>2</sub>.

#### **F. EPA overlooked risk reduction strategies evident in its Risk Assessment**

When Congress amended Section 6(a) of TSCA, it specified that EPA should only impose those risk mitigation measures necessary to reduce unreasonable risk to reasonable levels. However, the regulatory controls EPA has proposed to mitigate consumer exposures are draconian, and operate as an effective ban on retail sales of MeCl<sub>2</sub>- and NMP-containing paint strippers. EPA's Work Plan Chemicals Risk Assessment for MeCl<sub>2</sub> suggests two viable alternative risk reductions strategies that the Agency has failed to consider. First, the Risk Assessment notes that the use of a "vapor retardant" in retail MeCl<sub>2</sub> paint strippers could potentially reduce MeCl<sub>2</sub> emissions by more than 50%.<sup>125</sup> Section 6(a) of TSCA grants EPA the authority to impose restrictions on the chemical contents of product formulations, but EPA apparently did not consider proposing a regulation requiring that retail-size MeCl<sub>2</sub> paint strippers include a vapor suppressant capable of

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<sup>122</sup> In 2016, the Office of Management and Budget (OMB) issued a revised version of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." Circular A-119 and the *National Technology Transfer and Advancement Act* (NTTAA) of 1995 instruct U.S. federal agencies to consider using private-sector voluntary consensus standards instead of government-unique standards whenever possible. Office of Management & Budget, *Circular No. A-119 Revised* (Feb. 10, 1998), [https://obamawhitehouse.archives.gov/omb/circulars\\_a119](https://obamawhitehouse.archives.gov/omb/circulars_a119).

<sup>123</sup> 15 U.S.C. § 1262.

<sup>124</sup> EPA asserts that the Proposed Rule "does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d)." 82 Fed. Reg. at 7,528 (Jan. 19, 2017). However, EPA made this assertion prior to the initiation of the ASTM process. Since EPA does not intend to finalize the Proposed Rule until it has completed a subsequent rulemaking on paint strippers in the commercial refinishing industry, *see* 82 Fed. Reg. at 7,465, the Agency will likely need to conduct an NTTAA evaluation prior to promulgation of this Rule and at that point consider the ASTM standard. Accordingly, the most efficient use of Agency resources would be to suspend this rulemaking until the ASTM process is completed and the Agency can assess whether or to what extent adoption of the ASTM standard satisfies the Agency's obligations under TSCA.

<sup>125</sup> Environmental Protection Agency, *TSCA Work Plan Chemical Risk Assessment, Methylene Chloride: Paint-Stripping Use* (Aug. 2014), at Appendix H, p. 217.



reducing inhalation risks. Second, the Risk Assessment also concludes that EPA's modeling indicates that consumers potentially receive greater exposures during spray applications of paint strippers, when compared to brush-on formulations. However, there is no evidence in the record that EPA considered proposing that consumer-use paint strippers only be formulated and packaged for brush-on application and other forms of application that do not involve spray applications. These observations in EPA's Risk Assessment suggest that there may be a multitude of ways the Agency could fashion requirements for consumer-use paint strippers that are not as unnecessarily restrictive as the prohibition EPA wants to impose on retail-size containers of MeCl<sub>2</sub> and NMP paint strippers. TSCA Sections 6(a) and (c) require that EPA consider more fully whether less restrictive regulatory measures can mitigate risks to reasonable levels.

#### **IV. EPA has not Pursued in Good Faith, the Consultation with Other Federal Agencies that Section 9 of TSCA Requires.**

In the preamble of the NPRM, EPA argues that it need not engage in the consultation process with OSHA and the CPSC that Congress envisioned when enacting Section 9 because only TSCA provides the authority to address both consumer and commercial and governmental uses of MeCl<sub>2</sub> and NMP paint stripper products. In making this assertion, EPA over-reads the statute and its own authority, and undervalues the expertise of other governmental agencies in regulating chemicals. In doing so, EPA seeks to establish a precedent under the amended TSCA that will enable EPA to circumvent its obligations under Section 9 for all future rulemakings.

##### **A. EPA has not ensured that this rulemaking will not be duplicative of standards developed by OSHA and CPSC.**

TSCA § 9(a) requires that EPA determine whether unreasonable risk can be reduced to a sufficient extent under a law not administered by EPA. If the Agency so determines, EPA must submit a report to the agency(ies) responsible for administering the law, and request that the agency determine whether it can reduce the risk under such law. If the other agency determines that the activities outlined in the EPA referral report do not present the risk that the report describes, or takes action under the law(s) that it administers, EPA may not take actions under TSCA Section 6(a) to reduce that risk.<sup>126</sup> This provision is illustrative of the purpose of TSCA—to “fill[] gaps in Federal law that otherwise [do] not protect against the unreasonable risks presented by chemicals.”<sup>127</sup>

EPA has apparently concluded with such certainty that no law administered by another agency would be sufficient to manage the risks of MeCl<sub>2</sub>- or NMP-containing products that it did not even need to initiate a TSCA Section 9(a) referral to other agencies. EPA instead settled for the

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<sup>126</sup> 15 U.S.C. § 2608 (a)(1).

<sup>127</sup> H.R. Rep. No. 114-176, at 28.



minimum amount of consultation with other agencies—required under TSCA Section 9(d)—when it requested comment from OSHA and CPSC about how to best manage the risks of MeCl<sub>2</sub>- and NMP-containing products without imposing duplicative requirements on stakeholders that would be subject to this rulemaking.<sup>128</sup> EPA’s cavalier approach to the interagency consultation requirement undermines the purpose of the TSCA Section 9(a) analysis, and resulted in this case in a regulation that needlessly duplicates the risk management efforts of other agencies.

As OSHA’s March 31, 2016 response to EPA’s TSCA Section 9(d) consultation indicates, OSHA has substantial authority to address the risks associated with MeCl<sub>2</sub> when used in the workplace. This letter outlines several categories of persons for whom OSHA is not entitled to regulate exposure to MeCl<sub>2</sub>. However, it also acknowledges that the Occupational Safety and Health Act (OSH Act) gives it authority to “promulgate and enforce occupational safety and health standards to address exposure to unsafe levels of hazardous chemicals in the private sector and in most federal workplaces.”<sup>129</sup> Additionally, at the time that EPA initiated this TSCA Section 6(a) rulemaking, OSHA’s most recent modification to the MeCl<sub>2</sub> standard was already well-established.<sup>130</sup>

The CPSC also has authority with respect to the regulation of consumer-use paint-strippers under the Consumer Product Safety Act (CPSA) and the FHSA. As the CPSC’s June 3, 2016 response to EPA’s request for consultation under TSCA Section 9(d) lays out, the CPSC’s authority under these statutes includes issuing rules “reasonably necessary to prevent or reduce an unreasonable risk of injury associated with a consumer product,” and to require labeling, or even prohibit the use, of a hazardous substance in forms intended for household use.<sup>131</sup> The CPSC issued such rules on MeCl<sub>2</sub>-containing products in 1987, requiring that MeCl<sub>2</sub>-containing products be labeled as hazardous substances and include labels displaying information about the principal hazards posed by the use of these products.<sup>132</sup> As previously discussed, the Commission also began seeking comments on an update to these rules in September 2016 that would expand these labeling requirements to address acute as well as chronic risks.<sup>133</sup>

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<sup>128</sup> 82 Fed. Reg. 7,464, 7,520 (Jan. 19, 2017).

<sup>129</sup> Letter from David Michaels, Department of Labor, to James Jones, Environmental Protection Agency (March 31, 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0231-0153&contentType=pdf>.

<sup>130</sup> 29 C.F.R. §§ 1910.1052 (2012) (methylene chloride standard for general industry), 1915.1052 (2012) (methylene chloride standard for shipyard employment), 1926.1152 (2012) (methylene chloride standard for construction).

<sup>131</sup> Letter from Patricia H. Adkins, Consumer Product Safety Commission, to James J. Jones, Environmental Protection Agency (June 2016).

<sup>132</sup> 52 Fed. Reg. 34,698 (Sept. 14, 2017).

<sup>133</sup> 81 Fed. Reg. 60,298, 60,298-99 (Sept. 1, 2016).



EPA seems to conclude from its TSCA Section 9(d) consultation with OSHA and CPSC that: (1) OSHA and the CPSC do not individually have the authority to regulate exposure to MeCl<sub>2</sub> in all contexts; (2) the CPSA, FHSA and the OSH Act will not sufficiently reduce risks because these statutes require consideration of certain non-risk factors when regulating the use of chemical substances; and (3) it would be more efficient to promulgate all MeCl<sub>2</sub> standards under one law (TSCA), because EPA believes that these Agencies may not sufficiently prevent or reduce the risks posed by the use of MeCl<sub>2</sub>.<sup>134</sup> However these conclusions ignore the objectives of the requirements under TSCA Section 9.

First, although the OSHA standard does not cover consumers who use MeCl<sub>2</sub>- and NMP-containing products, or state or local government employees exposed to those products, it does cover, as the OSHA letter states, private industry and most federal government employees. Similarly, although the CPSC's authority under the CPSA and the FHSA addresses hazardous substances in forms intended or packaged for household use, the Commission acknowledges that its MeCl<sub>2</sub> regulations reach MeCl<sub>2</sub>-containing products sold online and in stores that are used by both consumers and workers. Notably, the FHSA imposes requirements on numerous home improvement and building products purchased at retail by both home owners and residential remodeler contractors and builders. Therefore the protection of CPSC's MeCl<sub>2</sub>-regulation also applies to professionals, such as self-employed users of MeCl<sub>2</sub>-containing products, who purchase these products online and in retail stores and who (under limited circumstances) may not be covered by OSHA.

However, EPA's obligation under TSCA Section 9(a) to consult with other agencies is based on the ability of those agencies to address the risks posed by uses within their jurisdiction, and is not curtailed based on the ability of other agencies to address all uses of a substance. If EPA's conclusion that a Section 9(a) consultation is only required when another agency can exercise authority to regulate the usage of a substance that is as broad as that granted to EPA under TSCA, Section 9 would become superfluous. This was certainly not Congress' purpose when it included the Section 9 requirements in its 1976 TSCA legislation, nor when it left these requirements intact in the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). Thus, EPA should have initiated TSCA Section 9(a) consultations with OSHA and CPSC to determine if they have sufficient tools to reduce the risks of MeCl<sub>2</sub>-containing products within their jurisdiction. Such a consultation would ensure, and still can ensure (if undertaken in good faith), consistent with TSCA Section 9, that EPA could "achieve maximum enforcement of TSCA while imposing the least burden of duplicative requirements."<sup>135</sup>

Additionally, in light of the new Executive Orders calling for streamlining and consolidation of regulations, the specific distribution of regulatory authority among OSHA, CPSC and EPA

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<sup>134</sup> 82 Fed. Reg. 7,464, 7,520-21 (Jan. 19, 2017).

<sup>135</sup> EPA, "TSCA Section 9 Relationship to Other Federal Laws," <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-9-relationship-other-federal-laws> (last updated May 19, 2016).



should be reassessed. It may no longer be the case that OSHA and the CPSC believe that they do not have the ability to effectively promulgate exposure standards for MeCl<sub>2</sub> in the workplace. OSHA and the CPSC have a long history of regulating this substance. Reliance on this agency expertise may be preferable to addressing this issue through TSCA. Thus, new leadership at the CPSC and at the Department of Labor may decide to take further action on their own to regulate MeCl<sub>2</sub> exposure, rather than simply deferring to EPA to take such action. In light of the recent changes in direction and emphasis with respect to federal rulemaking, EPA should initiate a new TSCA Section 9(a) consultation with OSHA and the CPSC or, at the very least, request updated input from OSHA and CPSC under TSCA Section 9(d) regarding the best approach to managing the risks of MeCl<sub>2</sub>-containing products without creating duplicative regulatory requirements.

Second, EPA's conclusion that its authority to address unreasonable risk under TSCA is "distinguishable" from the CPSC's authority under the CPSA and FHSA, and OSHA's authority under the OSH Act ignores its own requirements under TSCA Section 6(c)(2)(A) and 6(c)(2)(C). Although the 2016 TSCA amendments removed the requirement that EPA reduce the risks posed by the usage of a substance using the "least burdensome requirements," it did not eliminate the requirement that EPA consider non-risk factors when selecting risk management strategies and promulgating TSCA Section 6(a) regulations. Just as OSHA must consider the technological and economic feasibility of a Permissible Exposure Limit (PEL) before raising the PEL, EPA is required to consider the technological and economic feasibility of alternatives to a substance when taking action under TSCA Section 6(a) to regulate that substance.<sup>136</sup> Similarly, EPA is required to consider the "costs and benefits" of a TSCA Section 6(a) rulemaking<sup>137</sup>, just as the CPSC is required to include a finding in its rulemakings that the benefits of a regulation under the CPSA bear a "reasonable relationship" to its costs<sup>138</sup>. Thus, EPA's conclusion that it has a unique ability to address the unreasonable risks posed by the use of a substance discounts its obligations under TSCA Section 6(c).

Third, EPA's determination that the promulgation of MeCl<sub>2</sub> standards under one law (TSCA) is more efficient than applying standards developed under multiple laws and administered by multiple agencies is not relevant to a TSCA Section 9 analysis. Although the EPA Administrator has discretion to determine whether the risks of using a substance may be sufficiently mitigated under a law executed by another agency, if EPA so determines, the Agency is *required* to initiate a Section 9(a) consultation with that agency.<sup>139</sup> EPA does not have the discretion to decide that,

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<sup>136</sup> 15 U.S.C. § 2605 (c)(2)(C).

<sup>137</sup> *Id.* at § 2605 (c)(2)(A)(iv)(II).

<sup>138</sup> 82 Fed. Reg. at 7,521 (Jan. 19, 2017).

<sup>139</sup> 15 U.S.C. § 2608 (a)(1) (If the Administrator determines that... a chemical substance or mixture... presents an unreasonable risk of injury to health or the environment... and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator *shall* submit to the agency which administers such law a report which describes such risk) (emphasis added).



although the risks posed by a substance may be reduced under a law executed by another agency, it would be more convenient for EPA to issue its own regulations for that substance.

EPA's decision not to initiate a TSCA Section 9(a) consultation with OSHA and CPSC is not sufficiently justified in the preamble to this rulemaking, and ignores the spirit of TSCA Section 9. If EPA chooses not to initiate a TSCA Section 9(a) consultation for this rulemaking, when OSHA and CPSC both have well-established regulations relating to the use of MeCl<sub>2</sub>-containing products already in effect, it is difficult to imagine a situation in which EPA would feel compelled to initiate a TSCA Section 9(a) consultation. Thus, EPA's decision not to initiate a Section 9(a) consultation here threatens the usefulness of Section 9 requirements in future rulemakings. In fact, as is evidenced by the similarity between the language used to explain its decision not to undertake a Section 9(a) rulemaking here and the Agency's similar decision in its TSCA Section 6(a) rulemakings for TCE, EPA seems to be developing a pro forma rationale and template for use in all future Section 6(a) rulemakings to explain its decision not to undertake a Section 9(a) consultation.<sup>140</sup> EPA should reconsider its decision to forego a Section 9 consultation or, at the very least, the Agency should seek additional input from OSHA and CPSC about regulating the usage of MeCl<sub>2</sub>-containing products.

**B. EPA has not adequately taken into consideration its regulation of MeCl<sub>2</sub> under NESHAP standards**

Pursuant to TSCA § 9(b), if the unreasonable risk presented by a substance can be reduced to a sufficient extent under another law administered by EPA, then EPA shall use that other authority unless it determines that it is in the public interest to proceed under TSCA. In making this determination, EPA must compare the estimated costs and efficiencies of the actions to be taken under TSCA and the action to be taken under such other law. EPA has authority to regulate MeCl<sub>2</sub> emissions under the Clean Air Act (CAA) National Emission Standard for Hazard Air Pollutants (NESHAP) for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources.<sup>141</sup> The coverage of EPA's regulation of MeCl<sub>2</sub> emissions under NESHAP is fairly broad, applying to area sources engaging in paint stripping operations that use MeCl<sub>2</sub>-containing products, with limited exceptions. Operations covered by this NESHAP standard are required to implement practices to minimize MeCl<sub>2</sub> emissions and maintain records of MeCl<sub>2</sub> usage.

Many industries that would be regulated by this proposed TSCA Section 6(a) rulemaking are covered by the NESHAP regulations for paint stripping operations, including the automotive body, paint, and interior repair and maintenance industry (NAICS 811121), the office furniture industry (NAICS 811420), and the boat building industry (NAICS 336612).<sup>142</sup> The management

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<sup>140</sup> Compare 82 Fed. Reg. at 7,520 (Jan. 19, 2017) with 81 Fed. Reg. 91,592, 91,618 (Dec. 16, 2016).

<sup>141</sup> 40 C.F.R. § 63.11169.

<sup>142</sup> 82 Fed. Reg. 7,464 (Jan. 19, 2017); EPA, *Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal* (Jan. 9, 2017), at Appendix A.



practices that entities covered by NESHAP are required to implement include (1) only using MeCl<sub>2</sub>-containing paint strippers when alternatives are “incapable of accomplishing the work;” (2) optimizing paint stripper application conditions; (3) reducing exposure of MeCl<sub>2</sub>-containing paint strippers to the air; and (4) properly disposing of MeCl<sub>2</sub>-containing strippers.<sup>143</sup> Operations using more than 1 ton of MeCl<sub>2</sub> per year are required to develop a written management plan. Much like the TSCA Section 6(a) rulemaking proposed here, the NESHAP rulemaking encourages operations using MeCl<sub>2</sub>-containing paint strippers to consider alternatives like non-MeCl<sub>2</sub> paint strippers and non-chemical stripping methods like blasting.<sup>144</sup> NESHAP, however, leaves operations the option of using MeCl<sub>2</sub>-containing paint strippers in situations where an alternative stripping method would not be effective.

Although TSCA Section 9(b) gives EPA the discretion to decide that it is in the public interest to regulate MeCl<sub>2</sub> using TSCA rather than its NESHAP program or other EPA authorities, EPA should exercise this discretion with care while bearing in mind that TSCA is intended to fill gaps in existing federal law.<sup>145</sup> In light of this policy objective, EPA should reexamine whether it is in the public interest to issue a new rulemaking under TSCA Section 6(a) that will impose new requirements on industries that are already required to comply with the NESHAP MeCl<sub>2</sub> rulemaking.

### **C. EPA must adhere to the intent of OMB Circular A-119.**

OMB Circular A-119 requires federal agencies to, where possible, rely on the voluntary consensus standards of industry. Conforming with the spirit of OMB Circular A-119, EPA should support, not impede, voluntary industry-wide efforts being made to work collaboratively with CPSC on enhancements to labeling and risk communications measures that can be easily and effectively implemented in a timely manner. Moreover, as noted above, ASTM is in the process of developing a standard for the use of paint and coating removal products that contain MeCl<sub>2</sub>. ASTM is considering a system of labels and warnings based on best industry practices and years of practical experience. EPA has not considered this work by ASTM, and has seemingly dismissed the industry’s work with CPSC. The Agency should instead, at the very least, reconsider its conclusion that enhanced and improved warnings and labels do not constitute an effective means for addressing any hazards posed by MeCl<sub>2</sub>.

### **V. EPA Should Withdraw the Proposed Rule in Light of Executive Orders 13771 and 13777, which Instruct EPA to Reduce - Not Exacerbate - the Burden of Unnecessary Regulations on Small Businesses like Barr.**

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<sup>143</sup> 73 Fed. Reg. 1,738, 1,742 (Jan. 9, 2008).

<sup>144</sup> *Id.*

<sup>145</sup> H.R. Rep. No. 114-176, at 28.



EPA should withdraw the proposed MeCl<sub>2</sub> and NMP paint strippers rule because it is inconsistent with the public policy objectives and mandates of Executive Orders 13771 and 13777, issued by the White House on January 30, 2017 and February 24, 2017, respectively. Executive Order 13771 is intended to ensure the executive branch agencies are both prudent and financially responsible in managing the cost associated with complying with federal regulations. As articulated in Executive Order 13771 these responsibilities are applicable when an agency is issuing both final and proposed regulations. Accordingly, Section 1 of Executive Order 13771 states, “for every one new regulation issued, at least two prior regulations [shall] be identified for elimination.”<sup>146</sup> Section 2 of the Order requires that, “whenever an executive department or agency ... publicly *proposes* for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed.”<sup>147</sup> The Order also makes clear that the total incremental costs of all new regulations, “shall be no greater than zero,” and any new incremental costs associated with new regulations shall be offset by the elimination of existing costs associated with at least two previous regulations. EPA’s proposal identified no regulations the Agency intends to eliminate; in fact the NPRM makes clear EPA is determined to issue an additional regulation addressing MeCl<sub>2</sub>-containing paint strippers used for commercial furniture stripping.

Notwithstanding that the NPRM was issued prior to Executive Order 13771, it is readily apparent the proposed paint stripper rule, if issued in final form, cannot meet the fiscal responsibility and cost-effectiveness objectives that new regulations must meet under Executive Order 13771. As discussed previously in these comments, the Agency’s own Economic Analysis demonstrates that the cumulative costs of the features of the proposal affecting retail-size, consumer-use paint strippers will substantially outstrip any benefits. Thus, EPA cannot hope to issue a final regulation consistent with the NPRM and adhere to the cost reduction mandates specified in Section 2 of the Executive Order. As Barr’s comments, and the economic analysis provided by Ramboll Environ, make clear, EPA’s prohibition on retail-size consumer-use paint removal products will impose massive new economic burdens on Barr, as well as on our competitors in the industry. Countless downstream users of retail paint strippers that contain MeCl<sub>2</sub> will also experience increased economic burdens if forced to use more expensive alternatives that do not work as well as paint removers formulated with MeCl<sub>2</sub>, including alternative products that present significant health and safety risks. Entities expected to be impacted by this proposed rulemaking include a significant number of small businesses. For these reasons, EPA must withdraw the NPRM since the Agency’s proposed regulation cannot satisfy the economic mandates imposed by Executive Order 13771, and EPA does not have a plan in place to identify existing regulations for elimination upon promulgation of a final paint removal products rule.

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<sup>146</sup> Exec. Order No. 13771, 82 Fed. Reg. 9,339 (Feb. 3, 2017).

<sup>147</sup> *Id.* (emphasis added).





Even if the Agency does articulate a path forward for identifying two off-setting existing regulations for revocation to satisfy the Executive Order 13771 mandate (on which the Agency should permit time to solicit public comment in this context), the paint removal NPRM on its face cannot satisfy the objectives of Executive Order 13777. This Executive Order establishes that it is the policy of the United States to “alleviate unnecessary regulatory burdens placed on the American people.”<sup>148</sup> Executive Order 13777 requires each Agency to establish a Regulatory Reform Task Force to evaluate existing regulations for “repeal, replacement or modification.” Among the criteria for identifying regulations to be repealed or replaced are regulations that “impose costs that exceed benefits.”<sup>149</sup> The NPRM is thus inconsistent with Executive Order 13777 for two reasons. First, on its face, the proposal imposes costs that exceed its benefits. Second, and more broadly, the NPRM is the epitome of a new and unnecessary regulatory burden. The proposal would impose unnecessary economic risks on small businesses that currently produce retail-size paint removal products, jeopardizing numerous small businesses, the financial security of Barr’s employee-owners, and other similarly situated small business stakeholders. The rule will also deliberately take away from consumers the most effective paint stripping formulations on the retail market, eliminating consumers’ freedom of choice and forcing consumers and small business contractors to use substitute paint remover products that are less effective and less safe to use. In response to a petition pending before the CPSC, existing requirements already imposed by CPSC on retail-size paint removers can easily be amended and enhanced to mitigate risks to consumer users without the need to involve yet another federal agency in oversight of consumer-use paint stripper products. The CPSC standard, with technical assistance from EPA, could be extended to address the concerns the Agency has identified for consumers who might experience dermal exposures to retail-size NMP-containing paint strippers if they fail to wear appropriate gloves during use of those products.

Barr appreciates that EPA’s leadership now recognizes the important nature of Executive Orders 13771 and 13777 and is taking steps to quickly implement the White House’s regulatory reform policies. In our view, the paint remover NPRM represents a case study illustrative of the concerns expressed in the Agency’s April 11, 2017 press release announcing a public consultation process associated with the Administration’s regulatory reform agenda. We are pleased to learn that EPA is now committed to:

... the restoration of America’s economy through extensive reviews of the misaligned regulatory actions from the past administration ... Moving forward, ... listening to those directly impacted by regulations, and learning ways we can

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<sup>148</sup> Exec. Order No. 13777, 82 Fed. Reg. 12,285 (Feb. 24, 2017).

<sup>149</sup> *Id.* at § 3(d)(iii).



work together with our state and local partners, to ensure that we can provide clean air, land, and water to Americans.<sup>150</sup>

As EPA moves forward in this important process, we recommend that the Agency take a hard look at the paint removal NPRM and listen to affected stakeholders, like Barr, before taking any unnecessary regulatory actions. We are confident that upon review, it will become clear that the Agency should withdraw the provisions of the proposed stripper rule that pertain specifically to the prohibition on consumer-use, retail-size containers and work with our industry to implement an alternative strategy to address concerns for consumer users.

Finally, if EPA determines that its planned Risk Evaluation to be undertaken for MeCl<sub>2</sub> and NMP pursuant to Section 6(b)(2)(A) of the amended TSCA must consider and evaluate *all* conditions of use (including consumer uses of retail-size containers of paint stripper products), then the Agency should, for the sake of clarity and resource efficiency, provide notice of its intent to suspend the entire rulemaking until such time as the Section 6(b)(2) Risk Evaluation is completed. This will provide the Agency the time needed to more carefully consider the information Barr has provided and to more carefully evaluate the exposures residential users and consumers experience when they engage in paint stripping activities.

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## CONCLUSION

The Agency has before it the opportunity, in collaboration with the CPSC and the regulated community, to support a labeling standard that is specifically crafted for retail-size consumer-use MeCl<sub>2</sub>- and NMP-containing paint strippers. Enhanced by outreach to user groups, such a standard could establish an industry-wide labeling requirement, including designating the use of pictograms and multi-lingual text, collectively designed to address the concerns expressed by EPA about consumer and residential user exposures and label comprehension difficulties, and thus swiftly reduce consumer users risk to reasonable levels.

Barr supports a collaboration by EPA with CPSC to build on CPSC's current standard and specifically establish enhanced labeling standards that would: (1) require the use of MeCl<sub>2</sub>-containing products only in well-ventilated spaces and prohibit the use of products containing MeCl<sub>2</sub> in confined spaces such as bathrooms; (2) prohibit consumer and residential contractor uses of products containing MeCl<sub>2</sub> for stripping bathtubs; and (3) require the use of dermal protection for NMP-containing paint strippers. Such a rulemaking would be consistent with CPSC efforts with respect to labeling required under the FHSA and would provide a practical and rational approach to enhancing user awareness and risk avoidance techniques while meeting the amended TSCA Section 6(a) standard that EPA select and implement by regulation risk

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<sup>150</sup> EPA Press Release, "Regulatory Reform Underway at EPA," April 11, 2017 (<https://www.epa.gov/newsreleases/regulatory-reform-underway-epa>).



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mitigation measures *only* to the extent necessary so that the targeted chemical substance or mixture no longer presents such risk.



**EXHIBITS**

<b>Exhibit</b>	<b>Title</b>
1	Dr. Michael Lumpkin, Center for Toxicology & Environmental Health, <i>Comments on the Health Risk Basis for U.S. Environmental Protection Agency's Proposed Regulation of Methylene Chloride and N-Methylpyrrolidone Under TSCA 6(a)</i> , May 17, 2017.
2	Dr. Richard Kingston, Safety, Science & Toxicology Associates LLC, <i>Paint Stripping Agents &amp; Adverse Event Data Trends</i> , May 2017.  (Certain Passages Redacted, Contains TSCA CBI - non-redacted version submitted to EPA under separate cover)
3	Steven Hall, Applied Safety & Ergonomics, <i>Response to EPA Analysis Regarding Methylene Chloride Paint Remover Labeling as a Potential Risk Mitigation</i> , May 17, 2017.  (Certain Passages Redacted, Contains TSCA CBI - non-redacted version submitted to EPA under separate cover)
4	W.M. Barr, <i>Identification and Comparison of Solvents and Paint Removers as Alternatives to Methylene Chloride in Paint Removal Applications</i> , August 2015.
5	W.M. Barr, <i>Identification and Comparison of Solvents and Paint Removers as Alternatives to Methylene Chloride in Paint Removal Applications</i> , March 2017.
6	Mark Rockel, Ramboll Environ, <i>Economic Analysis of Proposed TSCA 6 Action on Methylene Chloride (MeCl<sub>2</sub>) and N-Methylpyrrolidone (NMP) in Paint and Coating Removal</i> (May 2017).  (Certain Passages Redacted, Contains TSCA CBI - non-redacted version submitted to EPA under separate cover)
7	R. Tom Long & Y. Pock Utiskul, Exponent, <i>EPA Paint Remover Flammability Analysis</i> (May 2017).
8	Halogenated Solvents Industry Alliance, <i>Petition to Amend the Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride Issued by the Commission Under the Federal Hazardous Substances Act</i> (July 2016).
9	QYR Chemical & Material Research Center, <i>2017 Market Research Report on Global Paint Remover Industry</i> (Feb. 2017)



10	ASTM International, <i>Designation: D6189-97 - Standard Practice for Evaluating the Efficiency of Chemical Removers for Organic Coatings</i> (Reapproved 2014) <i>(Submitted to EPA under separate cover due to copyright restrictions)</i>
11	W.M. Barr Paint Remover Unit Sales Data (2007-2016) <i>(Redacted, Contains TSCA CBI - non-redacted version submitted to EPA under separate cover)</i>
12	W.M. Barr, Updated Paint Stripper Labels (2016)
13	Paint Strippers - Market Share by Supplier (2015) <i>(Redacted, Contains TSCA CBI - non-redacted version submitted to EPA under separate cover)</i>

(Those reports and documents that are not redacted or excluded are included in their entirety.)